

US3322302 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:07:47

All time stamps listed in this document are displayed in GMT

US3322302

Form: Participant Creation

Data signed: (b) (4) 26 Feb 2021 03:53:09

Generated On: 09 Jun 2021 17:07:47

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Participant ID

US3322302

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

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US3322302

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Date of Birth (MMM yyyy)	(b) (6) 1983
Age	37
Age Units	YEARS
Age (Derived)	37
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) 26 Feb 2021 03:53:13

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	10 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" 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) 26 Feb 2021 03:53:13

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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) 26 Feb 2021 03:53:13

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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) 26 Feb 2021 03:53:13

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Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Condition	GASTRIC ULCER
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Condition	ACNE
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2010
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2010
Stop Year (derived)	2010

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Condition	MORPHINE ALLERGY
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Condition	TENDONITIS
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 03:53:13

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	13:29 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 13:29
Height ( <i>xxx.x</i> )	72.5 in
Weight ( <i>xxx.x</i> )	160.4 lb
BMI ( <i>xxx.x</i> )	21.49999 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 checked="" type="radio"/>
If Other, specify	ND - Not Done
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) 26 Feb 2021 03:53:13

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 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) 26 Feb 2021 03:53:13

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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**

PEDIATRICIAN WORKS IN  
HOSPITAL ICU, WORKS 5-7  
DAYS A WEEK.  
INTERACTS WITH 50+ PEOPLE  
PER WORKDAY

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

20 of 1951

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 03:53:13

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No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	True
Specify	PATIENT LIVES IN A HOUSE WITH HIS WIFE AND TWO KIDS. HIS WIFE IS A PHARMACIST AND ALSO WORKS FULL TIME IN A HOSPITAL. PT GOES GROCERY SHOPPING ONCE A WEEK.

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:53:13

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

What was the date of randomization? (dd MMM yyyy) 10 SEP 2020

What was the participant's randomization number? 145984

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

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

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

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

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

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

Liver Disease Yes ☐   
 No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐   
 No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

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) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

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)	10 SEP 2020
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 13:30
Temperature (xxx.x)	97.9 F
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)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	16:09 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 16:09
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 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) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 03:53:13

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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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 15:38 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 15:38

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) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	15:12 (24 HR)
Collection date and time (derived)	10 SEP 2020 15:12

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

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

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

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 17:07:47

**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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 16:00

PC Open Date & Time

10 SEP 2020 15:58

PC Close Date & Time

10 SEP 2020 18:28

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**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

98.2 °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	10 SEP 2020 23:58
PC Open Date & Time	10 SEP 2020 19:23
PC Close Date & Time	11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**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

98.2 °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

11 SEP 2020 16:15

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 14:16

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**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

98.6 °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

13 SEP 2020 15:07

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.3 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

14 SEP 2020 12:01

---

PC Open Date & Time

14 SEP 2020 12:00

---

PC Close Date & Time

15 SEP 2020 11:59

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US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

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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

98.2 °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

15 SEP 2020 13:25

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 20:03

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59



US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**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

10 SEP 2020 16:01

PC Open Date & Time

10 SEP 2020 15:58

PC Close Date & Time

10 SEP 2020 18:28

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**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

10 SEP 2020 23:59

PC Open Date & Time

10 SEP 2020 19:23

PC Close Date & Time

11 SEP 2020 11:59

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**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

11 SEP 2020 16:16

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**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

12 SEP 2020 14:17

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**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

13 SEP 2020 15:07

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**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

14 SEP 2020 12:01

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**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

15 SEP 2020 13:25

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**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

16 SEP 2020 20:03

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59



US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**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 ☐

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 16:02
PC Open Date & Time	10 SEP 2020 15:58
PC Close Date & Time	10 SEP 2020 18:28

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**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 ☐

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 23:59
PC Open Date & Time	10 SEP 2020 19:23
PC Close Date & Time	11 SEP 2020 11:59

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**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 17:07:47

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

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

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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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 14:17
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59



US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**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 ☒

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 15:08
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**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 ☒

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

Yes <input type="checkbox"/>	
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

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**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 ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

60 of 1951

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 13:25
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**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

62 of 1951

EAB) (1725)

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 20:03
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59



US3322302

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322302

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322302

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322302

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 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	VISIT2

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

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)	8 OCT 2020
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 15:00
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG



US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

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)	8 OCT 2020
Time of assessment (00:00-23:59)	16:15 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 16:15
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3322302

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3322302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

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) 08 OCT 2020

What was the treatment time? (00:00-23:59) 15:44 (24 HR)

Treatment Date and Time (derived) 08 OCT 2020 15:44

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

US3322302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

8 OCT 2020

Collection time (00:00-23:59)

15:40 (24 HR)

Collection date and time (derived)

8 OCT 2020 15:40

US3322302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Collection date (dd MMM yyyy)			8 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:35	8 OCT 2020 15:35
Nasopharyngeal Swab 2	No		

US3322302

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**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

08 OCT 2020 16:16

PC Open Date & Time

08 OCT 2020 16:04

PC Close Date & Time

08 OCT 2020 18:34

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**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 98.2 °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	08 OCT 2020 19:36
PC Open Date & Time	08 OCT 2020 19:29
PC Close Date & Time	09 OCT 2020 11:59



US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**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

97.9 °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

09 OCT 2020 12:12

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 OCT 2020 19:05

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**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

98.5 °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

11 OCT 2020 15:29

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**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

12 OCT 2020 23:35

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 OCT 2020 14:27

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**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

97.9 °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

14 OCT 2020 14:47

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**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

08 OCT 2020 16:16

PC Open Date & Time

08 OCT 2020 16:04

PC Close Date & Time

08 OCT 2020 18:34

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**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

08 OCT 2020 19:37

PC Open Date & Time

08 OCT 2020 19:29

PC Close Date & Time

09 OCT 2020 11:59



US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**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

09 OCT 2020 12:12

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**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

10 OCT 2020 19:05

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**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

11 OCT 2020 15:29

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**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

12 OCT 2020 23:35

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**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

13 OCT 2020 14:27

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**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

14 OCT 2020 14:47

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**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 ☐

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 16:16
PC Open Date & Time	08 OCT 2020 16:04
PC Close Date & Time	08 OCT 2020 18:34



US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**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 ☐

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

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

No ☒

Yes ☐

PC Time stamp	08 OCT 2020 19:37
PC Open Date & Time	08 OCT 2020 19:29
PC Close Date & Time	09 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**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 ☒

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 12:12
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**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 ☒

PRODUCTION RELEASE (v12.003

100 of 1951

EAB) (1725)

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 19:06
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**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 ☒

PRODUCTION RELEASE (v12.003

102 of 1951

EAB) (1725)

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 15:30
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59



US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**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 ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 23:36
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

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 ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 14:27
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**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 ☒

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

Yes <input type="checkbox"/>	
PC Time stamp	14 OCT 2020 14:47
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

DAY 8

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 ☐

PC Time Stamp 15 OCT 2020 21:39

PC Open Date & Time 15 OCT 2020 12:00

PC Close Date & Time 16 OCT 2020 11:59

US3322302

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:07:47

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	15 OCT 2020 21:39
PC Open Date & Time	15 OCT 2020 12:00
PC Close Date & Time	16 OCT 2020 11:59



US3322302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322302

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3322302

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

MULTIPLE UNSUCCESSFUL  
ATTEMPTS

*If Contact Not Made, please provide Comments*

US3322302

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

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

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	09:42 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 09:42
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 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)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3322302

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 NOV 2020

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

US3322302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 NOV 2020

Collection time (00:00-23:59)

10:30 (24 HR)

Collection date and time (derived)

11 NOV 2020 10:30

US3322302

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 NOV 2020 14:55:50
Patient Cloud Open Date & Time	10 NOV 2020 00:01
Patient Cloud Close Date & Time	14 NOV 2020 23:59

US3322302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 NOV 2020 20:21:12
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 14:16:11
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

DAY 82

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 18:50:50

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 14:27:45

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59



US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 02:16:50
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 DEC 2020 00:08:06

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 06:48:46

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 17:23:05
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 12:25:49
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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

16 JAN 2021 00:01:59

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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

25 JAN 2021 12:00:41

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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

30 JAN 2021 07:16:44

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59



US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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

Date and time of submission

06 FEB 2021 08:02:39

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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

13 FEB 2021 07:22:13

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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

20 FEB 2021 07:26:20

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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

01 MAR 2021 12:01:25

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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

06 MAR 2021 08:22:41

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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

13 MAR 2021 07:49:06

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 MAR 2021 08:42:42
Patient Cloud Open Date & Time	20 MAR 2021 00:01
Patient Cloud Close Date & Time	24 MAR 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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

27 MAR 2021 00:04:17

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59



US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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

Date and time of submission

03 APR 2021 06:27:48

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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

10 APR 2021 08:27:37

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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

18 APR 2021 10:29:18

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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

24 APR 2021 08:11:43

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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

03 MAY 2021 18:18:16

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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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15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 JUN 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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](#)

19 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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°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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	03 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 JUL 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
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 ☐



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 JUL 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	17 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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="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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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](#)

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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="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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	04 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 SEP 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	11 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 SEP 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	18 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59
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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 NOV 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐ Yes ☐

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

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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"/>



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 DEC 2021 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	04 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 DEC 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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="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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	11 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	18 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 DEC 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
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 ☐



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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](#)

25 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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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01 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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="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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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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08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 JAN 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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="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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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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15 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 JAN 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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](#)

29 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐  
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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	05 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 FEB 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAR 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAR 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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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12 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAR 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	26 MAR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 MAR 2022 23:59
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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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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02 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 APR 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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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09 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 APR 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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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23 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 APR 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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="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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 MAY 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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="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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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="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"/>



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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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21 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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°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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUN 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	04 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 JUN 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	11 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	18 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUN 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 JUN 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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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02 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JUL 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUL 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUL 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 AUG 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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="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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	13 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2022 23:59
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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 AUG 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	27 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 AUG 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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"/>



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	03 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 SEP 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐  
Yes ☐

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

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 SEP 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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"/>

**US3322302**

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**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	17 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 SEP 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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](#)

24 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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°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 ☐



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	01 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 OCT 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	15 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

---

26 OCT 2022 23:59

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US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	29 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 NOV 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**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 ☐

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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>	05 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 NOV 2022 23:59

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 <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"/>

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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

US3322302

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:07:47

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		01 MAR 2021 12:01:33

US3322302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322302

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3322302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322302

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 03 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3322302

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 03:53:13

Generated On: 09 Jun 2021 17:07:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322302

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322302

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322302

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 16:32:32

Generated On: 09 Jun 2021 17:07:47

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

Visit date (dd MMM yyyy)	01 APR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3322302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 16:32:32

Generated On: 09 Jun 2021 17:07:47

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) \_\_\_\_\_



US3322302

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 16:32:32

Generated On: 09 Jun 2021 17:07:47

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3322302

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 16:32:32

Generated On: 09 Jun 2021 17:07:47

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

Collection date (dd MMM yyyy)	01 APR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	09:36 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	01 APR 2021 09:36
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US3322302

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 16:32:32

Generated On: 09 Jun 2021 17:07:47

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322302

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

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*

**US3322302**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:07:47**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3322302

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:07:47

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"/>

**US3322302**

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

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

**Generated On: 09 Jun 2021 17:07:47**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3322302

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

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 03:53:12

Generated On: 09 Jun 2021 17:07:47

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

Visit date (dd MMM yyyy)	26 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3322302

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

Form: Unblinding

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

Date of updated informed consent (dd MMM yyyy) 26 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 26 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 03:53:09

Generated On: 09 Jun 2021 17:07:47

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 JAN 2021

Collection time (00:00-23:59)

08:36 (24 HR)

Collection date and time (derived)

26 JAN 2021 08:36

US3322302

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Feb 2021 03:53:09

Generated On: 09 Jun 2021 17:07:47

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

Collection date (dd MMM yyyy)	26 JAN 2021
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Collection time (00:00 - 23:59)	08:31
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Collection Date and Time (derived)	26 JAN 2021 08:31
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US3322302

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Feb 2021 03:53:09

Generated On: 09 Jun 2021 17:07:47

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3322302

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 03:53:09

Generated On: 09 Jun 2021 17:07:47

AEID	USA-US060-2020-MRNA-1273-P30 1000009
Adverse event	RIGHT SCAPHOID FRACTURE
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)	22 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)	10 DEC 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 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 type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 03:53:09

Generated On: 09 Jun 2021 17:07:47

Number of Days in ICU	
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 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 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	N/A
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

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Feb 2021 03:53:09

Generated On: 09 Jun 2021 17:07:47

---

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

Yes ☒

No ☐

---

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

---

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

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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US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
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 (2)

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

Name of Medication ESCITALOPRAM

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

	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 (3)

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

Name of Medication BUPROPION

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 150

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) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

	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) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

	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 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐  
No ☒

Indication ACID REFLUX

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 (5)

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

	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 (6)

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE AND INJECTION  
SITE PAIN

Dose per administration 400

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	08 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	09 OCT 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication RIGHT SCAPHOID FRACTURE

Dose per administration 10/325

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐  
No ☒

Indication RIGHT SCAPHOID FRACTURE

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 (8)

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

	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)	28 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
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="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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) 24 Mar 2021 22:06:56

Generated On: 09 Jun 2021 17:07:47

	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)	3 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	3 NOV 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"/>	

US3322302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Feb 2021 03:53:09

Generated On: 09 Jun 2021 17:07:47

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3322302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Feb 2021 03:53:09

Generated On: 09 Jun 2021 17:07:47

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
28 OCT 2020	RIGHT SCAPHOID SURGERY	Adverse Event	

US3322302

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:07:47

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

US3322302

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:07:47

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 ☐

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 26 Feb 2021 03:53:12

Generated On: 09 Jun 2021 17:07:47

SAEID	USA-US060-2020-MRNA-1273-P301000009
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Feb 2021 03:53:12

Generated On: 09 Jun 2021 17:07:47

SAEID	USA-US060-2020-MRNA-1273-P301000009
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/NOV/2020 11:24
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

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Feb 2021 03:53:12

Generated On: 09 Jun 2021 17:07:47

SAEID	USA-US060-2020-MRNA-1273-P301000009
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	02/DEC/2020 15:16
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



US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Feb 2021 03:53:12

Generated On: 09 Jun 2021 17:07:47

SAEID	USA-US060-2020-MRNA-1273-P301000009
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	03/DEC/2020 12:13
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

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Feb 2021 03:53:12

Generated On: 09 Jun 2021 17:07:47

SAEID	USA-US060-2020-MRNA-1273-P301000009
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 type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	TERESA
Investigator's Last Name	BECKER
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	28/DEC/2020 09:43
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

US3322302 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

**US3322302**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:07:47**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:48:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'US3322302'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:29:36

US3322302

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:01:57
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:08:34

US3322302

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:01:57
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:29:37

US3322302

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

[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 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:01:57
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:08:34

**US3322302**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:07:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'SCRN'	System	11 Sep 2020 15:08:34



US3322302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:47

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:04
User entered (b) (6) 1983'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:29:38

US3322302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:47

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:04
User entered '37'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:08:45

**US3322302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:07:47**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'YEARS'	System	11 Sep 2020 15:08:45

**US3322302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:07:47**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '37'	System	10 Sep 2020 20:56:56

US3322302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:47

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:04
User entered 'Male (M)'	Elisa Moralez (b) (4)	11 Sep 2020 15:08:45

US3322302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:47

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:04
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:08:45

US3322302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:47

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:04
User entered 'I'	Elisa Moralez (b) (4)	11 Sep 2020 15:08:45

US3322302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:47

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:04
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:08:45



**US3322302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:07:47**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:04
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:08:45

US3322302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:47

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:04
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:08:45

US3322302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:47

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:04
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:08:45

**US3322302**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:07:47**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:04
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:08:45

US3322302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:47

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:04
User entered empty.	Elisa Moralez (b) (4)	11 Sep 2020 15:08:45

US3322302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:47

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:04
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:08:45

US3322302

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:07:47

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:04
User entered '0'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:08:45

US3322302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:47

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:15
User entered '10 Sep 2020'	Frances Saubon (b) (4)	10 Sep 2020 20:56:56



**US3322302**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:07:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Sep 2020'	System	10 Sep 2020 20:56:56

**US3322302**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:07:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2020'	System	10 Sep 2020 20:56:56

US3322302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:47

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:15
User entered 'Amendment 3 (3)'	Frances Saubon (b) (4)	10 Sep 2020 20:56:56

US3322302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:15
User entered 'Yes (Y)'	Frances Saubon (b) (4)	10 Sep 2020 20:56:56

US3322302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:47

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:15
User entered empty.	Frances Saubon (b) (4)	10 Sep 2020 20:56:56

US3322302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:47

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:15
User entered empty.	Frances Saubon (b) (4)	10 Sep 2020 20:56:56

**US3322302**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:07:47**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:15
User entered 'No (N)'	Frances Saubon (b) (4)	10 Sep 2020 20:56:56

US3322302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:47

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:15
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 18:29:37



US3322302

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:07:47

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'I'	System	10 Sep 2020 20:57:00

US3322302

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:07:47

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:24
User entered 'Yes (Y)'	Frances Saubon (b) (4)	10 Sep 2020 20:57:00

US3322302

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:07:47

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:30
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Sep 2020 15:08:52

US3322302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:16:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:16:37
Data point term sent to Coder	System	11 Sep 2020 15:15:17
User entered 'Seasonal allergies'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:14:25

US3322302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2000'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:14:25

US3322302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:14:25

US3322302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:14:25

US3322302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered empty.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:14:25



US3322302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:14:25

US3322302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2000'	System	11 Sep 2020 15:14:25

**US3322302**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2000'	System	11 Sep 2020 15:14:25

US3322302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered empty.	System	11 Sep 2020 15:14:25

US3322302

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:07:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered empty.	System	11 Sep 2020 15:14:25

US3322302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Lower respiratory tract signs and symptoms, PT: Pulmonary haemorrhage, LLT: Pulmonary haemorrhage - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:31:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:31:44
Data point term sent to Coder	System	11 Sep 2020 15:15:17
User entered 'Idiopathic pulmonary Hemorrhage'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:14:39

US3322302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2011'	Elisa Moralez (b) (4)	11 Sep 2020 15:14:39

US3322302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:14:39



US3322302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:14:39

US3322302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2011'	Elisa Moralez (b) (4)	11 Sep 2020 15:14:39

US3322302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:14:39

US3322302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:47

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2011'	System	11 Sep 2020 15:14:39

US3322302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2011'	System	11 Sep 2020 15:14:39

US3322302

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:07:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2011'	System	11 Sep 2020 15:14:39

**US3322302**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:07:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2011'	System	11 Sep 2020 15:14:39

US3322302

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Respiratory tract therapeutic procedures, HLT: Bronchial and pulmonary therapeutic procedures, PT: Lung lobectomy, LLT: Lung lower lobectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 21:07:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 21:07:37
Data point term sent to Coder	System	11 Sep 2020 15:15:19
User entered 'Left Lung lower Lobectomy'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:14:52



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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2011'	Elisa Moralez (b) (4)	11 Sep 2020 15:14:52

US3322302

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:14:52

**US3322302**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:07:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'No (N)'	Elisa Moralez (b) (4)	11 Sep 2020 15:14:52

US3322302

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2011'	Elisa Moralez (b) (4)	11 Sep 2020 15:14:52

US3322302

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:14:52

US3322302

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:47

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2011'	System	11 Sep 2020 15:14:52

US3322302

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2011'	System	11 Sep 2020 15:14:52

US3322302

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:07:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2011'	System	11 Sep 2020 15:14:52



**US3322302**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:07:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2011'	System	11 Sep 2020 15:14:52

US3322302

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric ulcer, LLT: Gastric ulcer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:16:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:16:36
Data point term sent to Coder	System	11 Sep 2020 15:15:21
User entered 'gastric Ulcer'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:15:03

US3322302

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2016'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:03

US3322302

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:03

US3322302

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:15:03

US3322302

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered empty.	Elisa Moralez (b) (4)	11 Sep 2020 15:15:03

US3322302

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:03

**US3322302**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:07:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2016'	System	11 Sep 2020 15:15:03



**US3322302**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:07:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2016'	System	11 Sep 2020 15:15:03

US3322302

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:07:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered empty.	System	11 Sep 2020 15:15:03

**US3322302**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:07:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered empty.	System	11 Sep 2020 15:15:03

US3322302

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:16:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:16:36
Data point term sent to Coder	System	11 Sep 2020 15:15:19
User entered 'acid reflux'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:15:14

US3322302

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2016'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:14

US3322302

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:14

US3322302

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:14

US3322302

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered empty.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:15:14



US3322302

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:14

US3322302

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:07:47

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2016'	System	11 Sep 2020 15:15:14

**US3322302**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:07:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2016'	System	11 Sep 2020 15:15:14

**US3322302**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:07:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered empty.	System	11 Sep 2020 15:15:14

**US3322302**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:07:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered empty.	System	11 Sep 2020 15:15:14

US3322302

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:17:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:17:40
Data point term sent to Coder	System	11 Sep 2020 15:16:23
User entered 'Acne'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:15:37

US3322302

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2000'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:37

US3322302

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:37



US3322302

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'No (N)'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:37

US3322302

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2010'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:37

US3322302

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:37

US3322302

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2000'	System	11 Sep 2020 15:15:37

US3322302

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:07:47

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2000'	System	11 Sep 2020 15:15:37

**US3322302**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:07:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2010'	System	11 Sep 2020 15:15:37

**US3322302**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:07:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2010'	System	11 Sep 2020 15:15:37

US3322302

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:07:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:17:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:17:37
Data point term sent to Coder	System	11 Sep 2020 15:16:27
User entered 'Depression'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:15:48



US3322302

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2012'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:15:48

US3322302

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:48

US3322302

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:07:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:15:48

US3322302

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:07:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered empty.	Elisa Moralez (b) (4)	11 Sep 2020 15:15:48

US3322302

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:07:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:48

**US3322302**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:07:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2012'	System	11 Sep 2020 15:15:48

US3322302

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:07:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2012'	System	11 Sep 2020 15:15:48

**US3322302**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:07:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered empty.	System	11 Sep 2020 15:15:48



**US3322302**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:07:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered empty.	System	11 Sep 2020 15:15:48

US3322302

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:07:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:17:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:17:38
Data point term sent to Coder	System	11 Sep 2020 15:16:28
User entered 'Anxiety'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:15:58

US3322302

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2012'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:58

US3322302

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:58

US3322302

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:07:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:15:58

US3322302

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:07:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered empty.	Elisa Moralez (b) (4)	11 Sep 2020 15:15:58

US3322302

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:07:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:15:58

**US3322302**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:07:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2012'	System	11 Sep 2020 15:15:58



US3322302

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:07:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2012'	System	11 Sep 2020 15:15:58

**US3322302**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:07:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered empty.	System	11 Sep 2020 15:15:58

US3322302

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:07:47

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered empty.	System	11 Sep 2020 15:15:58

US3322302

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:07:47

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:17:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:17:37
Data point term sent to Coder	System	11 Sep 2020 15:16:28
User entered 'Appendectomy'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:16:16

US3322302

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2000'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:16:16

US3322302

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:16:16

US3322302

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:07:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:16:16

US3322302

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:07:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2000'	Elisa Moralez (b) (4)	11 Sep 2020 15:16:16



US3322302

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:07:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:16:16

US3322302

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:07:47

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2000'	System	11 Sep 2020 15:16:16

**US3322302**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:07:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2000'	System	11 Sep 2020 15:16:16

US3322302

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:07:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2000'	System	11 Sep 2020 15:16:16

**US3322302**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:07:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2000'	System	11 Sep 2020 15:16:16

US3322302

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:07:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to analgesics - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:17:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 15:17:39
Data point term sent to Coder	System	11 Sep 2020 15:16:31
User entered 'Morphine allergy'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:16:27

US3322302

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2011'	Elisa Moralez (b) (4)	11 Sep 2020 15:16:27

US3322302

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:16:27



US3322302

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:07:47

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Sep 2020 15:16:27

US3322302

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:07:47

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered empty.	Elisa Moralez (b) (4)	11 Sep 2020 15:16:27

US3322302

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:07:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:16:27

US3322302

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:07:47

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2011'	System	11 Sep 2020 15:16:27

US3322302

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:07:47

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2011'	System	11 Sep 2020 15:16:27

US3322302

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:07:47

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered empty.	System	11 Sep 2020 15:16:27

**US3322302**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:07:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered empty.	System	11 Sep 2020 15:16:27

US3322302

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:07:47

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Tendon, ligament and cartilage disorders, HLT: Tendon disorders, PT: Tendonitis, LLT: Tendonitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:57:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 18:57:54
Data point term sent to Coder	System	07 Dec 2020 18:56:23
User entered 'Tendonitis'	Frances Saubon (b) (4) (b) (4)	07 Dec 2020 18:56:10



US3322302

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2000'	Frances Saubon (b) (4)	07 Dec 2020 18:56:10

US3322302

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Frances Saubon (b) (4)	07 Dec 2020 18:56:10

**US3322302**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:07:47**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'No (N)'	Frances Saubon (b) (4)	07 Dec 2020 18:56:10

**US3322302**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:07:47**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered 'UN UNK 2000'	Frances Saubon (b) (4)	07 Dec 2020 18:56:10

US3322302

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:07:47

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:36
User entered '0'	Frances Saubon (b) (4)	07 Dec 2020 18:56:10

**US3322302**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:07:47**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2000'	System	07 Dec 2020 18:56:10

**US3322302**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:07:47**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2000'	System	07 Dec 2020 18:56:10

**US3322302**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:07:47**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'Jan 2000'	System	07 Dec 2020 18:56:10



**US3322302**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:07:47**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '2000'	System	07 Dec 2020 18:56:10

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:44
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:01

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:44
User entered '10 Sep 2020'	Elisa Moralez (b) (4)	11 Sep 2020 15:17:01

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:44
User entered '13:29'	Elisa Moralez (b) (4)	11 Sep 2020 15:17:01

**US3322302**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:07:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '10 Sep 2020 13:29'	System	11 Sep 2020 15:17:01

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:44
User entered '72.5' in	Elisa Moralez (b) (4)	11 Sep 2020 15:17:01
DataPoint set to visible.	(b) (4) System	10 Sep 2020 20:57:00

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:44
User entered '160.4' lb	Elisa Moralez (b) (4)	11 Sep 2020 15:17:01
DataPoint set to visible.	(b) (4) System	10 Sep 2020 20:57:00

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '21.49999'	System	11 Sep 2020 15:17:01
DataPoint set to visible.	System	10 Sep 2020 20:57:00



US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'kg/m2'	System	11 Sep 2020 15:17:01
DataPoint set to visible.	System	10 Sep 2020 20:57:00

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:44
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:01

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:44
User entered 'Other (Other)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:01

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:44
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	11 Sep 2020 15:17:01

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:44
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:01

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'bpm'	System	11 Sep 2020 15:17:01

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:44
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:01

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'breaths/min'	System	11 Sep 2020 15:17:01



US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:44
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:01

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'mmHg'	System	11 Sep 2020 15:17:01

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:44
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:01

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'mmHg'	System	11 Sep 2020 15:17:01

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30

US3322302

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30

US3322302

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:52
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Sep 2020 15:17:11

US3322302

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:52
User entered '10 Sep 2020'	Elisa Moralez (b) (4)	11 Sep 2020 15:17:11



US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38



US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered 'Pediatrician works in hospital ICU, works 5-7 days a week. Interacts with 50+ people per workday'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '0'	Elisa Moralez (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered '0'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered '0'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38



US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

**Resides in high density housing** (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered '0'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered '0'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered '0'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'I'	Elisa Moralez (b) (4)	11 Sep 2020 15:17:38

US3322302

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:07:47

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:02:58
User entered 'Patient lives in a house with his wife and two kids. His wife is a pharmacist and also works full time in a hospital. Pt goes grocery shopping once a week.'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:38

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:03:14
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Sep 2020 15:17:51

US3322302

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:03:14
User entered '10 Sep 2020'	Elisa Moralez (b) (4)	11 Sep 2020 15:17:51

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:14
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:17:51



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'VISIT1'	System	11 Sep 2020 15:17:51

US3322302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:20
User entered '10 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 20:14:34

US3322302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:47

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:20
User entered '145984'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 20:14:34

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:47

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:20
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Sep 2020 20:14:34

US3322302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:47

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)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:20
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:18:25

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:47

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)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:20
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:18:25

US3322302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:47

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:20
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:18:25

US3322302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:47

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:03:20
User entered 'No (N)'	Elisa Moralez (b) (4)	11 Sep 2020 15:18:25



US3322302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:47

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:03:20
User entered 'No (N)'	Elisa Moralez (b) (4)	11 Sep 2020 15:18:25

US3322302

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:07:47

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:20
User entered 'No (N)'	Elisa Moralez (b) (4)	26 Sep 2020 17:44:38
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 06:02:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:02:40

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Sep 2020 15:19:33



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered '10 Sep 2020'	Elisa Moralez (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered '13:30'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '10 Sep 2020 13:30'	System	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered '97.9' F	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered empty.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered '63'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'bpm'	System	11 Sep 2020 15:19:33



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered '20'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'breaths/min'	System	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered '116'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'mmHg'	System	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered '74'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'mmHg'	System	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:47

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:07:47

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Morales (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered '10 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered '16:09'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '10 Sep 2020 16:09'	System	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered '98.3' F	Elisa Moralez (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered 'Oral (Oral)'	Elisa Moralez (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered empty.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33



US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered '58'	Elisa Moralez (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'bpm'	System	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered '20'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'breaths/min'	System	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered '110'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'mmHg'	System	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:29
User entered '70'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:19:33

US3322302

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'mmHg'	System	11 Sep 2020 15:19:33



US3322302

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:03:39
User entered 'No (N)'	Elisa Moralez (b) (4)	11 Sep 2020 15:19:37

US3322302

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:03:39
User entered empty.	Elisa Moralez (b) (4)	11 Sep 2020 15:19:37

US3322302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:47
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	10 Sep 2020 20:57:24

US3322302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:03:47
User entered empty.	Frances Saubon (b) (4)	10 Sep 2020 20:57:24

US3322302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

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)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	10 Sep 2020 20:57:24

US3322302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 20:57:24

US3322302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:47
User entered '10 Sep 2020'	Frances Saubon (b) (4) (b) (4)	10 Sep 2020 20:57:24

US3322302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:47
User entered '15:38'	Frances Saubon (b) (4) (b) (4)	10 Sep 2020 20:57:24



US3322302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '10 Sep 2020 15:38'	System	10 Sep 2020 20:57:24

US3322302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:47
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4) (b) (4)	10 Sep 2020 20:57:24

US3322302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		09 Feb 2021 03:03:47
User entered 'ONCE'	System	10 Sep 2020 20:57:24

US3322302

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 20:57:24

US3322302

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:57
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:20:04

US3322302

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:03:57
User entered '10 Sep 2020'	Elisa Moralez (b) (4)	11 Sep 2020 15:20:04

US3322302

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:03:57
User entered '15:12'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:20:04

**US3322302**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:07:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '10 Sep 2020 15:12'	System	11 Sep 2020 15:20:04



US3322302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:07:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:03
User entered '10 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:20:13

US3322302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Elisa Morales (b) (4) (b) (4)	11 Sep 2020 15:20:13

US3322302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:03
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:20:13

US3322302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:03
User entered '15:10'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:20:13

US3322302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '10 Sep 2020 15:10'	System	11 Sep 2020 15:20:13

US3322302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:47

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Elisa Morales (b) (4) (b) (4)	11 Sep 2020 15:20:13

US3322302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:03
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:20:13

US3322302

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:03
User entered empty.	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:20:13



**US3322302**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:07:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered empty.	System	11 Sep 2020 15:20:13

US3322302

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:09
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Sep 2020 15:20:19

US3322302

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '1'	System	11 Sep 2020 15:20:19

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:00:44', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '62db4f2c-e08e-4edd-8582-4a056c9b7a10' User entered 'Yes (Y)'	System	10 Sep 2020 21:01:05
	System	10 Sep 2020 21:01:05

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:00:49', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '62db4f2c-e08e-4edd-8582-4a056c9b7a10' User entered '98.3'	System	10 Sep 2020 21:01:05
	System	10 Sep 2020 21:01:05

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:00:55', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '62db4f2c-e08e-4edd-8582-4a056c9b7a10'	System	10 Sep 2020 21:01:05
User entered 'No (N)'	System	10 Sep 2020 21:01:05

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:00:58', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '62db4f2c-e08e-4edd-8582-4a056c9b7a10' User entered '10 Sep 2020 16:00'	System	10 Sep 2020 21:01:05
	System	10 Sep 2020 21:01:05



US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '10 Sep 2020 15:58'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '10 Sep 2020 18:28'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:58:37', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'cb16c385-663f-42ac-9b1f-e8c2b18059cd' User entered 'Yes (Y)'	System	11 Sep 2020 04:58:53
	System	11 Sep 2020 04:58:53

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:58:43', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'cb16c385-663f-42ac-9b1f-e8c2b18059cd' User entered '98.2'	System	11 Sep 2020 04:58:53
	System	11 Sep 2020 04:58:53

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:58:46', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'cb16c385-663f-42ac-9b1f-e8c2b18059cd' User entered 'No (N)'	System	11 Sep 2020 04:58:53
	System	11 Sep 2020 04:58:53

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:58:49', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'cb16c385-663f-42ac-9b1f-e8c2b18059cd' User entered '10 Sep 2020 23:58'	System	11 Sep 2020 04:58:53
	System	11 Sep 2020 04:58:53

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '10 Sep 2020 19:23'	System	10 Sep 2020 20:57:24



US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 2'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:15:04', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b8f26716-e111-4fd0-bc36-cecd4a294aea' User entered 'Yes (Y)'	System	11 Sep 2020 21:15:30
	System	11 Sep 2020 21:15:30

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:15:09', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b8f26716-e111-4fd0-bc36-cecd4a294aea' User entered '98.2'	System	11 Sep 2020 21:15:30
	System	11 Sep 2020 21:15:30

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:15:12', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b8f26716-e111-4fd0-bc36-cecd4a294aea' User entered 'No (N)'	System	11 Sep 2020 21:15:30
	System	11 Sep 2020 21:15:30

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:15:25', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b8f26716-e111-4fd0-bc36-cecd4a294aea' User entered '11 Sep 2020 16:15'	System	11 Sep 2020 21:15:30
	System	11 Sep 2020 21:15:30

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:57:24



US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 3'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:16:37', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '22a070c1-f08b-4fdf-a2d7-06adb4d0a068' User entered 'Yes (Y)'	System	12 Sep 2020 19:16:49
	System	12 Sep 2020 19:16:49

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:16:41', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '22a070c1-f08b-4fdf-a2d7-06adb4d0a068' User entered '98.6'	System	12 Sep 2020 19:16:49
	System	12 Sep 2020 19:16:49

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:16:43', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '22a070c1-f08b-4fdf-a2d7-06adb4d0a068' User entered 'No (N)'	System	12 Sep 2020 19:16:49
	System	12 Sep 2020 19:16:49

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:16:46', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '22a070c1-f08b-4fdf-a2d7-06adb4d0a068' User entered '12 Sep 2020 14:16'	System	12 Sep 2020 19:16:49
	System	12 Sep 2020 19:16:49

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 4'	System	10 Sep 2020 20:57:24



US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:07:29', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '15744609-b670-452b-bfb3-752530e44670' User entered 'Yes (Y)'	System	13 Sep 2020 20:07:50
	System	13 Sep 2020 20:07:50

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:07:33', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '15744609-b670-452b-bfb3-752530e44670' User entered '98.6'	System	13 Sep 2020 20:07:50
	System	13 Sep 2020 20:07:50

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:07:35', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '15744609-b670-452b-bfb3-752530e44670'	System	13 Sep 2020 20:07:50
User entered 'No (N)'	System	13 Sep 2020 20:07:50

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:07:46', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '15744609-b670-452b-bfb3-752530e44670' User entered '13 Sep 2020 15:07'	System	13 Sep 2020 20:07:50
	System	13 Sep 2020 20:07:50

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 5'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:00:54', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'e8751e95-0b26-494b-a614-29e096dd2925'	System	14 Sep 2020 17:01:50
User entered 'Yes (Y)'	System	14 Sep 2020 17:01:50



US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:00:59', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'e8751e95-0b26-494b-a614-29e096dd2925' User entered '98.3'	System	14 Sep 2020 17:01:50
	System	14 Sep 2020 17:01:50

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:01', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'e8751e95-0b26-494b-a614-29e096dd2925'	System	14 Sep 2020 17:01:50
User entered 'No (N)'	System	14 Sep 2020 17:01:50

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:04', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'e8751e95-0b26-494b-a614-29e096dd2925' User entered '14 Sep 2020 12:01'	System	14 Sep 2020 17:01:50
	System	14 Sep 2020 17:01:50

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 6'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:02', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '24c9407b-1520-4026-85d4-545c81e39ab4' User entered 'Yes (Y)'	System	15 Sep 2020 18:25:19
	System	15 Sep 2020 18:25:19

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:05', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '24c9407b-1520-4026-85d4-545c81e39ab4' User entered '98.2'	System	15 Sep 2020 18:25:19
	System	15 Sep 2020 18:25:19



US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:10', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '24c9407b-1520-4026-85d4-545c81e39ab4'	System	15 Sep 2020 18:25:19
User entered 'No (N)'	System	15 Sep 2020 18:25:19

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:13', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '24c9407b-1520-4026-85d4-545c81e39ab4'	System	15 Sep 2020 18:25:19
User entered '15 Sep 2020 13:25'	System	15 Sep 2020 18:25:19

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 7'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:20', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '666bd3f7-00c9-4920-8f78-d0f2f7ef6694' User entered 'Yes (Y)'	System	17 Sep 2020 01:03:33
	System	17 Sep 2020 01:03:33

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:25', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '666bd3f7-00c9-4920-8f78-d0f2f7ef6694' User entered '98.2'	System	17 Sep 2020 01:03:33
	System	17 Sep 2020 01:03:33

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:28', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '666bd3f7-00c9-4920-8f78-d0f2f7ef6694'	System	17 Sep 2020 01:03:33
User entered 'No (N)'	System	17 Sep 2020 01:03:33



US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:30', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '666bd3f7-00c9-4920-8f78-d0f2f7ef6694' User entered '16 Sep 2020 20:03'	System	17 Sep 2020 01:03:33
	System	17 Sep 2020 01:03:33

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:01:38', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a981d80c-d1da-4718-8f3e-0adbe26449f0' User entered 'None (1)'	System	10 Sep 2020 21:01:49
	System	10 Sep 2020 21:01:49

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:01:41', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a981d80c-d1da-4718-8f3e-0adbe26449f0' User entered 'No (N)'	System	10 Sep 2020 21:01:49
	System	10 Sep 2020 21:01:49

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:01:43', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a981d80c-d1da-4718-8f3e-0adbe26449f0' User entered 'No (N)'	System	10 Sep 2020 21:01:49
	System	10 Sep 2020 21:01:49

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:01:45', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a981d80c-d1da-4718-8f3e-0adbe26449f0' User entered 'None (1)'	System	10 Sep 2020 21:01:49
	System	10 Sep 2020 21:01:49



US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:01:48', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a981d80c-d1da-4718-8f3e-0adbe26449f0' User entered '10 Sep 2020 16:01'	System	10 Sep 2020 21:01:49
	System	10 Sep 2020 21:01:49

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '10 Sep 2020 15:58'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '10 Sep 2020 18:28'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:59:02', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'dcc0546d-19d8-43fd-aca9-e214d4940ef2'	System	11 Sep 2020 04:59:21
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 04:59:21

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:59:07', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'dcc0546d-19d8-43fd-aca9-e214d4940ef2'	System	11 Sep 2020 04:59:21
User entered 'No (N)'	System	11 Sep 2020 04:59:21

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:59:10', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'dcc0546d-19d8-43fd-aca9-e214d4940ef2' User entered 'No (N)'	System	11 Sep 2020 04:59:21
	System	11 Sep 2020 04:59:21

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:59:13', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'dcc0546d-19d8-43fd-aca9-e214d4940ef2' User entered 'None (1)'	System	11 Sep 2020 04:59:21
	System	11 Sep 2020 04:59:21



US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:59:17', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'dcc0546d-19d8-43fd-aca9-e214d4940ef2'	System	11 Sep 2020 04:59:21
User entered '10 Sep 2020 23:59'	System	11 Sep 2020 04:59:21

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '10 Sep 2020 19:23'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 2'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:15:43', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '668a9f27-0607-49eb-9e4a-dd845efff9bf'	System	11 Sep 2020 21:16:06
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 21:16:06

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:15:46', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '668a9f27-0607-49eb-9e4a-dd845efff9bf' User entered 'No (N)'	System	11 Sep 2020 21:16:06
	System	11 Sep 2020 21:16:06

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:15:49', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '668a9f27-0607-49eb-9e4a-dd845efff9bf' User entered 'No (N)'	System	11 Sep 2020 21:16:06
	System	11 Sep 2020 21:16:06

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:15:58', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '668a9f27-0607-49eb-9e4a-dd845efff9bf'	System	11 Sep 2020 21:16:06
User entered 'None (1)'	System	11 Sep 2020 21:16:06



US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:16:02', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '668a9f27-0607-49eb-9e4a-dd845efff9bf'	System	11 Sep 2020 21:16:06
User entered '11 Sep 2020 16:16'	System	11 Sep 2020 21:16:06

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 3'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:16:50', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1411282b-b33a-4782-9983-7a5c24e2cc15'	System	12 Sep 2020 19:17:04
User entered 'Does not interfere with activity (2)'	System	12 Sep 2020 19:17:04

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:16:54', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1411282b-b33a-4782-9983-7a5c24e2cc15' User entered 'No (N)'	System	12 Sep 2020 19:17:04
	System	12 Sep 2020 19:17:04

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:16:56', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1411282b-b33a-4782-9983-7a5c24e2cc15' User entered 'No (N)'	System	12 Sep 2020 19:17:04
	System	12 Sep 2020 19:17:04

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:16:59', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1411282b-b33a-4782-9983-7a5c24e2cc15' User entered 'None (1)'	System	12 Sep 2020 19:17:04
	System	12 Sep 2020 19:17:04



US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:17:02', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1411282b-b33a-4782-9983-7a5c24e2cc15' User entered '12 Sep 2020 14:17'	System	12 Sep 2020 19:17:04
	System	12 Sep 2020 19:17:04

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 4'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:07:51', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9ef9d8ca-f84d-433b-a8c4-429be0447e40'	System	13 Sep 2020 20:08:02
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 20:08:02

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:07:53', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9ef9d8ca-f84d-433b-a8c4-429be0447e40'	System	13 Sep 2020 20:08:02
User entered 'No (N)'	System	13 Sep 2020 20:08:02

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:07:55', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9ef9d8ca-f84d-433b-a8c4-429be0447e40' User entered 'No (N)'	System	13 Sep 2020 20:08:02
	System	13 Sep 2020 20:08:02

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:07:57', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9ef9d8ca-f84d-433b-a8c4-429be0447e40' User entered 'None (1)'	System	13 Sep 2020 20:08:02
	System	13 Sep 2020 20:08:02



US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:07:59', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9ef9d8ca-f84d-433b-a8c4-429be0447e40' User entered '13 Sep 2020 15:07'	System	13 Sep 2020 20:08:02
	System	13 Sep 2020 20:08:02

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 5'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:10', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1c288ff4-5a6f-4c74-b59e-9b31d78467d4'	System	14 Sep 2020 17:02:22
User entered 'None (1)'	System	14 Sep 2020 17:02:22

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:12', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1c288ff4-5a6f-4c74-b59e-9b31d78467d4' User entered 'No (N)'	System	14 Sep 2020 17:02:22
	System	14 Sep 2020 17:02:22

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:14', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1c288ff4-5a6f-4c74-b59e-9b31d78467d4' User entered 'No (N)'	System	14 Sep 2020 17:02:22
	System	14 Sep 2020 17:02:22

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:17', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1c288ff4-5a6f-4c74-b59e-9b31d78467d4' User entered 'None (1)'	System	14 Sep 2020 17:02:22
	System	14 Sep 2020 17:02:22



US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:19', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1c288ff4-5a6f-4c74-b59e-9b31d78467d4' User entered '14 Sep 2020 12:01'	System	14 Sep 2020 17:02:22
	System	14 Sep 2020 17:02:22

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 6'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:17', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '3e1912a2-0753-4304-a140-24fdcb2afb84' User entered 'None (1)'	System	15 Sep 2020 18:25:34
	System	15 Sep 2020 18:25:34

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:19', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '3e1912a2-0753-4304-a140-24fdb2afb84' User entered 'No (N)'	System	15 Sep 2020 18:25:34
	System	15 Sep 2020 18:25:34

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:21', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '3e1912a2-0753-4304-a140-24fdb2afb84' User entered 'No (N)'	System	15 Sep 2020 18:25:34
	System	15 Sep 2020 18:25:34

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:30', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '3e1912a2-0753-4304-a140-24fdcb2afb84' User entered 'None (1)'	System	15 Sep 2020 18:25:34
	System	15 Sep 2020 18:25:34



**US3322302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:32', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '3e1912a2-0753-4304-a140-24fdb2afb84' User entered '15 Sep 2020 13:25'	System	15 Sep 2020 18:25:34
	System	15 Sep 2020 18:25:34

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 7'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:33', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4df1ef51-041d-4063-98bf-c6f375e6d455'	System	17 Sep 2020 01:03:44
User entered 'None (1)'	System	17 Sep 2020 01:03:44

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:36', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4df1ef51-041d-4063-98bf-c6f375e6d455'	System	17 Sep 2020 01:03:44
User entered 'No (N)'	System	17 Sep 2020 01:03:44

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:38', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4df1ef51-041d-4063-98bf-c6f375e6d455'	System	17 Sep 2020 01:03:44
User entered 'No (N)'	System	17 Sep 2020 01:03:44

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:39', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4df1ef51-041d-4063-98bf-c6f375e6d455'	System	17 Sep 2020 01:03:44
User entered 'None (1)'	System	17 Sep 2020 01:03:44



**US3322302**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:42', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4df1ef51-041d-4063-98bf-c6f375e6d455'	System	17 Sep 2020 01:03:44
User entered '16 Sep 2020 20:03'	System	17 Sep 2020 01:03:44

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:01:57', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f4a7c3c2-b405-42a9-8256-724ecbc1f082' User entered 'None (0)'	System	10 Sep 2020 21:02:15
	System	10 Sep 2020 21:02:15

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:02:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f4a7c3c2-b405-42a9-8256-724ecbc1f082' User entered 'None (0)'	System	10 Sep 2020 21:02:15
	System	10 Sep 2020 21:02:15

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:02:01', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f4a7c3c2-b405-42a9-8256-724ecbc1f082' User entered 'None (0)'	System	10 Sep 2020 21:02:15
	System	10 Sep 2020 21:02:15

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:02:02', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f4a7c3c2-b405-42a9-8256-724ecbc1f082' User entered 'None (0)'	System	10 Sep 2020 21:02:15
	System	10 Sep 2020 21:02:15



US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:02:04', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f4a7c3c2-b405-42a9-8256-724ecbc1f082' User entered 'None (0)'	System	10 Sep 2020 21:02:15
	System	10 Sep 2020 21:02:15

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:02:06', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f4a7c3c2-b405-42a9-8256-724ecbc1f082' User entered 'None (0)'	System	10 Sep 2020 21:02:15
	System	10 Sep 2020 21:02:15

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:02:11', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f4a7c3c2-b405-42a9-8256-724ecbc1f082' User entered 'No (N)'	System	10 Sep 2020 21:02:15
	System	10 Sep 2020 21:02:15

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T16:02:13', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f4a7c3c2-b405-42a9-8256-724ecbc1f082' User entered '10 Sep 2020 16:02'	System	10 Sep 2020 21:02:15
	System	10 Sep 2020 21:02:15

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '10 Sep 2020 15:58'	System	10 Sep 2020 20:57:24

**US3322302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '10 Sep 2020 18:28'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:59:24', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '612a9241-3570-455f-813d-b0e36c3b8235' User entered 'None (0)'	System	11 Sep 2020 04:59:44
	System	11 Sep 2020 04:59:44



US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:59:27', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '612a9241-3570-455f-813d-b0e36c3b8235' User entered 'None (0)'	System	11 Sep 2020 04:59:44
	System	11 Sep 2020 04:59:44

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:59:30', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '612a9241-3570-455f-813d-b0e36c3b8235' User entered 'None (0)'	System	11 Sep 2020 04:59:44
	System	11 Sep 2020 04:59:44

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:59:31', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '612a9241-3570-455f-813d-b0e36c3b8235' User entered 'None (0)'	System	11 Sep 2020 04:59:44
	System	11 Sep 2020 04:59:44

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:59:34', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '612a9241-3570-455f-813d-b0e36c3b8235' User entered 'None (0)'	System	11 Sep 2020 04:59:44
	System	11 Sep 2020 04:59:44

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:59:35', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '612a9241-3570-455f-813d-b0e36c3b8235' User entered 'None (0)'	System	11 Sep 2020 04:59:44
	System	11 Sep 2020 04:59:44

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:59:40', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '612a9241-3570-455f-813d-b0e36c3b8235' User entered 'No (N)'	System	11 Sep 2020 04:59:44
	System	11 Sep 2020 04:59:44

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-10T23:59:42', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '612a9241-3570-455f-813d-b0e36c3b8235' User entered '10 Sep 2020 23:59'	System	11 Sep 2020 04:59:44
	System	11 Sep 2020 04:59:44

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '10 Sep 2020 19:23'	System	10 Sep 2020 20:57:24



**US3322302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 2'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:16:29', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '76e6a215-569b-414f-a544-31f123bf82a8' User entered 'None (0)'	System	11 Sep 2020 21:16:50
	System	11 Sep 2020 21:16:50

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:16:31', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '76e6a215-569b-414f-a544-31f123bf82a8' User entered 'None (0)'	System	11 Sep 2020 21:16:50
	System	11 Sep 2020 21:16:50

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:16:34', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '76e6a215-569b-414f-a544-31f123bf82a8' User entered 'None (0)'	System	11 Sep 2020 21:16:50
	System	11 Sep 2020 21:16:50

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:16:36', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '76e6a215-569b-414f-a544-31f123bf82a8' User entered 'None (0)'	System	11 Sep 2020 21:16:50
	System	11 Sep 2020 21:16:50

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:16:38', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '76e6a215-569b-414f-a544-31f123bf82a8' User entered 'None (0)'	System	11 Sep 2020 21:16:50
	System	11 Sep 2020 21:16:50

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:16:40', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '76e6a215-569b-414f-a544-31f123bf82a8' User entered 'None (0)'	System	11 Sep 2020 21:16:50
	System	11 Sep 2020 21:16:50



US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:16:43', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '76e6a215-569b-414f-a544-31f123bf82a8' User entered 'No (N)'	System	11 Sep 2020 21:16:50
	System	11 Sep 2020 21:16:50

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-11T16:16:46', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '76e6a215-569b-414f-a544-31f123bf82a8' User entered '11 Sep 2020 16:16'	System	11 Sep 2020 21:16:50
	System	11 Sep 2020 21:16:50

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 3'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:17:05', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '74026f74-5ca4-49ff-8223-6ef1f0aff64a' User entered 'None (0)'	System	12 Sep 2020 19:17:22
	System	12 Sep 2020 19:17:22

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:17:07', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '74026f74-5ca4-49ff-8223-6ef1f0aff64a' User entered 'None (0)'	System	12 Sep 2020 19:17:22
	System	12 Sep 2020 19:17:22

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:17:09', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '74026f74-5ca4-49ff-8223-6ef1f0aff64a' User entered 'None (0)'	System	12 Sep 2020 19:17:22
	System	12 Sep 2020 19:17:22



US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:17:11', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '74026f74-5ca4-49ff-8223-6ef1f0aff64a' User entered 'None (0)'	System	12 Sep 2020 19:17:22
	System	12 Sep 2020 19:17:22

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:17:13', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '74026f74-5ca4-49ff-8223-6ef1f0aff64a' User entered 'None (0)'	System	12 Sep 2020 19:17:22
	System	12 Sep 2020 19:17:22

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:17:14', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '74026f74-5ca4-49ff-8223-6ef1f0aff64a' User entered 'None (0)'	System	12 Sep 2020 19:17:22
	System	12 Sep 2020 19:17:22

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:17:16', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '74026f74-5ca4-49ff-8223-6ef1f0aff64a' User entered 'No (N)'	System	12 Sep 2020 19:17:22
	System	12 Sep 2020 19:17:22

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-12T14:17:19', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '74026f74-5ca4-49ff-8223-6ef1f0aff64a' User entered '12 Sep 2020 14:17'	System	12 Sep 2020 19:17:22
	System	12 Sep 2020 19:17:22

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

**US3322302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 4'	System	10 Sep 2020 20:57:24



US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:08:10', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1330e666-e698-402b-a241-a1ff53c35fe6' User entered 'None (0)'	System	13 Sep 2020 20:08:25
	System	13 Sep 2020 20:08:25

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:08:12', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1330e666-e698-402b-a241-a1ff53c35fe6' User entered 'None (0)'	System	13 Sep 2020 20:08:25
	System	13 Sep 2020 20:08:25

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:08:14', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1330e666-e698-402b-a241-a1ff53c35fe6' User entered 'None (0)'	System	13 Sep 2020 20:08:25
	System	13 Sep 2020 20:08:25

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:08:16', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1330e666-e698-402b-a241-a1ff53c35fe6' User entered 'None (0)'	System	13 Sep 2020 20:08:25
	System	13 Sep 2020 20:08:25

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:08:17', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1330e666-e698-402b-a241-a1ff53c35fe6' User entered 'None (0)'	System	13 Sep 2020 20:08:25
	System	13 Sep 2020 20:08:25

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:08:20', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1330e666-e698-402b-a241-a1ff53c35fe6' User entered 'None (0)'	System	13 Sep 2020 20:08:25
	System	13 Sep 2020 20:08:25

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:08:22', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1330e666-e698-402b-a241-a1ff53c35fe6' User entered 'No (N)'	System	13 Sep 2020 20:08:25
	System	13 Sep 2020 20:08:25

**US3322302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-13T15:08:24', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '1330e666-e698-402b-a241-a1ff53c35fe6' User entered '13 Sep 2020 15:08'	System	13 Sep 2020 20:08:25
	System	13 Sep 2020 20:08:25



US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

**US3322302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 5'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:23', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2d235208-ac6b-4d36-90db-2076bc759485' User entered 'None (0)'	System	14 Sep 2020 17:02:57
	System	14 Sep 2020 17:02:57

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:26', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2d235208-ac6b-4d36-90db-2076bc759485' User entered 'None (0)'	System	14 Sep 2020 17:02:57
	System	14 Sep 2020 17:02:57

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:28', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2d235208-ac6b-4d36-90db-2076bc759485' User entered 'None (0)'	System	14 Sep 2020 17:02:57
	System	14 Sep 2020 17:02:57

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:32', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2d235208-ac6b-4d36-90db-2076bc759485' User entered 'None (0)'	System	14 Sep 2020 17:02:57
	System	14 Sep 2020 17:02:57

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:33', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2d235208-ac6b-4d36-90db-2076bc759485' User entered 'None (0)'	System	14 Sep 2020 17:02:57
	System	14 Sep 2020 17:02:57



US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:35', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2d235208-ac6b-4d36-90db-2076bc759485' User entered 'None (0)'	System	14 Sep 2020 17:02:57
	System	14 Sep 2020 17:02:57

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:38', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2d235208-ac6b-4d36-90db-2076bc759485' User entered 'No (N)'	System	14 Sep 2020 17:02:57
	System	14 Sep 2020 17:02:57

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-14T12:01:40', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2d235208-ac6b-4d36-90db-2076bc759485' User entered '14 Sep 2020 12:01'	System	14 Sep 2020 17:02:57
	System	14 Sep 2020 17:02:57

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 6'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:35', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '5e3b6fb1-26e0-49e9-81ba-6e12d959dd35' User entered 'None (0)'	System	15 Sep 2020 18:25:50
	System	15 Sep 2020 18:25:50

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:37', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '5e3b6fb1-26e0-49e9-81ba-6e12d959dd35' User entered 'None (0)'	System	15 Sep 2020 18:25:50
	System	15 Sep 2020 18:25:50



US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:38', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '5e3b6fb1-26e0-49e9-81ba-6e12d959dd35' User entered 'None (0)'	System	15 Sep 2020 18:25:50
	System	15 Sep 2020 18:25:50

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:39', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '5e3b6fb1-26e0-49e9-81ba-6e12d959dd35' User entered 'None (0)'	System	15 Sep 2020 18:25:50
	System	15 Sep 2020 18:25:50

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:41', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '5e3b6fb1-26e0-49e9-81ba-6e12d959dd35' User entered 'None (0)'	System	15 Sep 2020 18:25:50
	System	15 Sep 2020 18:25:50

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:42', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '5e3b6fb1-26e0-49e9-81ba-6e12d959dd35' User entered 'None (0)'	System	15 Sep 2020 18:25:50
	System	15 Sep 2020 18:25:50

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:45', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '5e3b6fb1-26e0-49e9-81ba-6e12d959dd35' User entered 'No (N)'	System	15 Sep 2020 18:25:50
	System	15 Sep 2020 18:25:50

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-15T13:25:47', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '5e3b6fb1-26e0-49e9-81ba-6e12d959dd35' User entered '15 Sep 2020 13:25'	System	15 Sep 2020 18:25:50
	System	15 Sep 2020 18:25:50

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

**US3322302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 20:57:24



US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 7'	System	10 Sep 2020 20:57:24

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:45', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '371a0c0a-e386-4061-8348-56839e91aa25' User entered 'None (0)'	System	17 Sep 2020 01:04:01
	System	17 Sep 2020 01:04:01

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:47', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '371a0c0a-e386-4061-8348-56839e91aa25' User entered 'None (0)'	System	17 Sep 2020 01:04:01
	System	17 Sep 2020 01:04:01

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:48', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '371a0c0a-e386-4061-8348-56839e91aa25' User entered 'None (0)'	System	17 Sep 2020 01:04:01
	System	17 Sep 2020 01:04:01

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:50', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '371a0c0a-e386-4061-8348-56839e91aa25' User entered 'None (0)'	System	17 Sep 2020 01:04:01
	System	17 Sep 2020 01:04:01

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:51', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '371a0c0a-e386-4061-8348-56839e91aa25' User entered 'None (0)'	System	17 Sep 2020 01:04:01
	System	17 Sep 2020 01:04:01

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:53', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '371a0c0a-e386-4061-8348-56839e91aa25' User entered 'None (0)'	System	17 Sep 2020 01:04:01
	System	17 Sep 2020 01:04:01

US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:55', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '371a0c0a-e386-4061-8348-56839e91aa25' User entered 'No (N)'	System	17 Sep 2020 01:04:01
	System	17 Sep 2020 01:04:01



US3322302

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-09-16T20:03:57', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '371a0c0a-e386-4061-8348-56839e91aa25' User entered '16 Sep 2020 20:03'	System	17 Sep 2020 01:04:01
	System	17 Sep 2020 01:04:01

**US3322302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 20:57:24

**US3322302**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:50:28
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:16:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 22:29:16

US3322302

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:16:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '17 Sep 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 22:29:16

US3322302

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:16:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 22:29:16

US3322302

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:16:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 22:29:16

US3322302

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:16:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Sep 2020 22:29:37



US3322302

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '1'	System	17 Sep 2020 22:29:37

**US3322302**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:07:47**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:28
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 16:46:18

US3322302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:28
User entered '24 Sep 2020'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 16:46:18

US3322302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:28
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 16:46:18

US3322302

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:28
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Sep 2020 16:46:18

US3322302

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:04:33
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	25 Sep 2020 16:46:36

**US3322302**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:07:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'I'	System	25 Sep 2020 16:46:36

US3322302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:04:42
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	05 Oct 2020 15:47:35



US3322302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:04:42
User entered '1 Oct 2020'	Elisa Moralez (b) (4)	05 Oct 2020 15:47:35

US3322302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:42
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	05 Oct 2020 15:47:35

US3322302

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:42
User entered empty.	Elisa Moralez (b) (4) (b) (4)	05 Oct 2020 15:47:35

US3322302

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4), (b) (6)	09 Feb 2021 03:04:48
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	05 Oct 2020 15:47:54

US3322302

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'I'	System	05 Oct 2020 15:47:54

US3322302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:56
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 21:59:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:56
User entered '8 Oct 2020'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 21:59:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:04:56
User entered 'Clinic (Clinic)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 21:59:52



**US3322302**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:07:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'VISIT2'	System	08 Oct 2020 21:59:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User accepted default value 'Pre-Dose (PREDOSE)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered '8 Oct 2020'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered '15:00'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '8 Oct 2020 15:00'	System	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered '98.2' F	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered 'Oral (Oral)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52



US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered empty.	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered '68'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'bpm'	System	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered '14'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'breaths/min'	System	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered '126'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'mmHg'	System	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered '85'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52



US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:07:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'mmHg'	System	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User accepted default value 'Post-Dose (POSTDOSE)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered '8 Oct 2020'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered '16:15'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '8 Oct 2020 16:15'	System	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered '98.8' F	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered 'Oral (Oral)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52



US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered empty.	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered '62'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'bpm'	System	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered '13'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'breaths/min'	System	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered '112'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'mmHg'	System	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:02
User entered '75'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:01:52



US3322302

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:07:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'mmHg'	System	08 Oct 2020 22:01:52

US3322302

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:08
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:02:03

US3322302

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:08
User entered '8 Oct 2020'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:02:03

US3322302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:15
User entered 'Yes (Y)'	Frances Saubon (b) (6) (b) (6)	08 Oct 2020 20:53:28

US3322302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:15
User entered empty.	Frances Saubon (b) (4) (b) (4)	08 Oct 2020 20:53:28

US3322302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

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)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:15
User entered empty.	Frances Saubon (b) (4) (b) (4)	08 Oct 2020 20:53:28

US3322302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'MRNA-1273 OR PLACEBO'	System	08 Oct 2020 20:53:28

US3322302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:15
User closed query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).' (Site from DM).		16 Oct 2020 15:25:26
Query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).' ' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 17:06:08
User entered '08 Oct 2020' reason for change: Data Entry Error		15 Oct 2020 17:05:59
User opened query 'Per CDM: Please consider updating the date format to DD-MM-YYYY, including 2 digits for day (for example 01-JAN-2020).' (Site from DM).		15 Oct 2020 14:20:50
User entered '8 Oct 2020'	Frances Saubon (b) (4) (b) (4)	08 Oct 2020 20:53:28



US3322302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:15
User entered '15:44'	Frances Saubon (b) (4) (b) (4)	08 Oct 2020 20:53:28

US3322302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '08 Oct 2020 15:44'	System	15 Oct 2020 17:05:59
User entered '8 Oct 2020 15:44'	System	08 Oct 2020 20:53:28

US3322302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:15
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4) (b) (4)	08 Oct 2020 20:53:28

US3322302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		09 Feb 2021 03:05:15
User entered 'ONCE'	System	08 Oct 2020 20:53:28

US3322302

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:07:47

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'INTRAMUSCULAR'	System	08 Oct 2020 20:53:28

US3322302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:24
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:02:24

US3322302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:24
User entered '8 Oct 2020'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:02:24

US3322302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:05:24
User entered '15:40'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:02:24



US3322302

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '8 Oct 2020 15:40'	System	08 Oct 2020 22:02:24

US3322302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:07:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:06:18
User entered '8 Oct 2020'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:02:48

**US3322302**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:02:48

US3322302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:06:18
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:02:48

US3322302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:07:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:06:18
User entered '15:35'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:02:48

**US3322302**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '8 Oct 2020 15:35'	System	08 Oct 2020 22:02:48

**US3322302**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:07:47**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:02:48

US3322302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:06:18
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:02:48



US3322302

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:07:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:06:18
User entered empty.	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 22:02:48

**US3322302**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:07:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered empty.	System	08 Oct 2020 22:02:48

US3322302

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 03:06:26
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	08 Oct 2020 21:59:40

US3322302

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '1'	System	08 Oct 2020 21:59:40

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:03', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '23437381-add9-4f13-b9bc-5b4a799fef2e' User entered 'Yes (Y)'	System	08 Oct 2020 21:16:17
	System	08 Oct 2020 21:16:17

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:07', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '23437381-add9-4f13-b9bc-5b4a799fef2e' User entered '98.8'	System	08 Oct 2020 21:16:17
	System	08 Oct 2020 21:16:17

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:10', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '23437381-add9-4f13-b9bc-5b4a799fef2e' User entered 'No (N)'	System	08 Oct 2020 21:16:17
	System	08 Oct 2020 21:16:17



US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:13', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '23437381-add9-4f13-b9bc-5b4a799fef2e' User entered '08 Oct 2020 16:16'	System	08 Oct 2020 21:16:17
	System	08 Oct 2020 21:16:17

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '08 Oct 2020 16:04'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '08 Oct 2020 18:34'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:36:42', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '64fccdbf-3e90-4c7b-b815-537b17177b74' User entered 'Yes (Y)'	System	09 Oct 2020 00:36:53
	System	09 Oct 2020 00:36:53

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:36:47', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '64fccdbf-3e90-4c7b-b815-537b17177b74' User entered '98.2'	System	09 Oct 2020 00:36:53
	System	09 Oct 2020 00:36:53

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:36:49', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '64fccdbf-3e90-4c7b-b815-537b17177b74' User entered 'No (N)'	System	09 Oct 2020 00:36:53
	System	09 Oct 2020 00:36:53

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:36:51', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '64fccdbf-3e90-4c7b-b815-537b17177b74' User entered '08 Oct 2020 19:36'	System	09 Oct 2020 00:36:53
	System	09 Oct 2020 00:36:53



US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '08 Oct 2020 19:29'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 2'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:11:59', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'c6632181-5fab-4b6d-b81a-0fbac3b07254' User entered 'Yes (Y)'	System	09 Oct 2020 17:12:17
	System	09 Oct 2020 17:12:17

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:06', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'c6632181-5fab-4b6d-b81a-0fbac3b07254' User entered '97.9'	System	09 Oct 2020 17:12:17
	System	09 Oct 2020 17:12:17

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:09', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'c6632181-5fab-4b6d-b81a-0fbac3b07254' User entered 'No (N)'	System	09 Oct 2020 17:12:17
	System	09 Oct 2020 17:12:17

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:11', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'c6632181-5fab-4b6d-b81a-0fbac3b07254' User entered '09 Oct 2020 12:12'	System	09 Oct 2020 17:12:17
	System	09 Oct 2020 17:12:17

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 20:53:28



US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 3'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:05:20', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '74165a78-4490-4b2f-8e47-22b993187a87' User entered 'Yes (Y)'	System	11 Oct 2020 00:05:36
	System	11 Oct 2020 00:05:36

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:05:25', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '74165a78-4490-4b2f-8e47-22b993187a87' User entered '98.2'	System	11 Oct 2020 00:05:36
	System	11 Oct 2020 00:05:36

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:05:29', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '74165a78-4490-4b2f-8e47-22b993187a87'	System	11 Oct 2020 00:05:36
User entered 'No (N)'	System	11 Oct 2020 00:05:36

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:05:31', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '74165a78-4490-4b2f-8e47-22b993187a87' User entered '10 Oct 2020 19:05'	System	11 Oct 2020 00:05:36
	System	11 Oct 2020 00:05:36

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 20:53:28



US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 4'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:29:23', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9541d0de-15ad-42c7-91f7-2327ac84cae4' User entered 'Yes (Y)'	System	11 Oct 2020 20:29:35
	System	11 Oct 2020 20:29:35

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:29:28', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9541d0de-15ad-42c7-91f7-2327ac84cae4' User entered '98.5'	System	11 Oct 2020 20:29:35
	System	11 Oct 2020 20:29:35

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:29:31', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9541d0de-15ad-42c7-91f7-2327ac84cae4' User entered 'No (N)'	System	11 Oct 2020 20:29:35
	System	11 Oct 2020 20:29:35

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:29:33', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9541d0de-15ad-42c7-91f7-2327ac84cae4' User entered '11 Oct 2020 15:29'	System	11 Oct 2020 20:29:35
	System	11 Oct 2020 20:29:35

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 5'	System	08 Oct 2020 20:53:28



US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:35:26', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'd5763e8b-b9a8-47e9-b7e0-f497c9bd3315' User entered 'Yes (Y)'	System	13 Oct 2020 04:35:41
	System	13 Oct 2020 04:35:41

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:35:33', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'd5763e8b-b9a8-47e9-b7e0-f497c9bd3315' User entered '97.9'	System	13 Oct 2020 04:35:41
	System	13 Oct 2020 04:35:41

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:35:36', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'd5763e8b-b9a8-47e9-b7e0-f497c9bd3315' User entered 'No (N)'	System	13 Oct 2020 04:35:41
	System	13 Oct 2020 04:35:41

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:35:38', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'd5763e8b-b9a8-47e9-b7e0-f497c9bd3315' User entered '12 Oct 2020 23:35'	System	13 Oct 2020 04:35:41
	System	13 Oct 2020 04:35:41

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 6'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:26:56', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b85a9180-a83d-4fb4-adb2-788f6a18d175' User entered 'Yes (Y)'	System	13 Oct 2020 19:27:12
	System	13 Oct 2020 19:27:12



US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b85a9180-a83d-4fb4-adb2-788f6a18d175' User entered '98.3'	System	13 Oct 2020 19:27:12
	System	13 Oct 2020 19:27:12

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:04', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b85a9180-a83d-4fb4-adb2-788f6a18d175'	System	13 Oct 2020 19:27:12
User entered 'No (N)'	System	13 Oct 2020 19:27:12

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:06', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b85a9180-a83d-4fb4-adb2-788f6a18d175' User entered '13 Oct 2020 14:27'	System	13 Oct 2020 19:27:12
	System	13 Oct 2020 19:27:12

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 7'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:46:56', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b9a29ff4-f67b-437c-be90-3fbf40a26722' User entered 'Yes (Y)'	System	14 Oct 2020 19:47:09
	System	14 Oct 2020 19:47:09

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:02', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b9a29ff4-f67b-437c-be90-3fbf40a26722' User entered '97.9'	System	14 Oct 2020 19:47:09
	System	14 Oct 2020 19:47:09



US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:04', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b9a29ff4-f67b-437c-be90-3fbf40a26722'	System	14 Oct 2020 19:47:09
User entered 'No (N)'	System	14 Oct 2020 19:47:09

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:06', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b9a29ff4-f67b-437c-be90-3fbf40a26722'	System	14 Oct 2020 19:47:09
User entered '14 Oct 2020 14:47'	System	14 Oct 2020 19:47:09

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:17', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'bfb0fa61-d1b1-448a-a280-d22c248ded1a' User entered 'None (1)'	System	08 Oct 2020 21:16:31
	System	08 Oct 2020 21:16:31

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:20', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'bfb0fa61-d1b1-448a-a280-d22c248ded1a' User entered 'No (N)'	System	08 Oct 2020 21:16:31
	System	08 Oct 2020 21:16:31

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:23', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'bfb0fa61-d1b1-448a-a280-d22c248ded1a' User entered 'No (N)'	System	08 Oct 2020 21:16:31
	System	08 Oct 2020 21:16:31



US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:26', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'bfb0fa61-d1b1-448a-a280-d22c248ded1a' User entered 'None (1)'	System	08 Oct 2020 21:16:31
	System	08 Oct 2020 21:16:31

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:28', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'bfb0fa61-d1b1-448a-a280-d22c248ded1a' User entered '08 Oct 2020 16:16'	System	08 Oct 2020 21:16:31
	System	08 Oct 2020 21:16:31

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '08 Oct 2020 16:04'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '08 Oct 2020 18:34'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:36:55', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'c8c7a41b-544b-49c4-96f4-ff161ae851bd'	System	09 Oct 2020 00:37:06
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 00:37:06

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:36:57', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'c8c7a41b-544b-49c4-96f4-ff161ae851bd' User entered 'No (N)'	System	09 Oct 2020 00:37:06
	System	09 Oct 2020 00:37:06

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:36:58', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'c8c7a41b-544b-49c4-96f4-ff161ae851bd' User entered 'No (N)'	System	09 Oct 2020 00:37:06
	System	09 Oct 2020 00:37:06



US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:37:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'c8c7a41b-544b-49c4-96f4-ff161ae851bd' User entered 'None (1)'	System	09 Oct 2020 00:37:06
	System	09 Oct 2020 00:37:06

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:37:02', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'c8c7a41b-544b-49c4-96f4-ff161ae851bd' User entered '08 Oct 2020 19:37'	System	09 Oct 2020 00:37:06
	System	09 Oct 2020 00:37:06

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '08 Oct 2020 19:29'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 2'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:28', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a312c2d3-0dd2-4469-82bd-73cdc9d395dd'	System	09 Oct 2020 17:12:42
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 17:12:42

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:31', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a312c2d3-0dd2-4469-82bd-73cdc9d395dd' User entered 'No (N)'	System	09 Oct 2020 17:12:42
	System	09 Oct 2020 17:12:42

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:33', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a312c2d3-0dd2-4469-82bd-73cdc9d395dd' User entered 'No (N)'	System	09 Oct 2020 17:12:42
	System	09 Oct 2020 17:12:42



US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:35', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a312c2d3-0dd2-4469-82bd-73cdc9d395dd' User entered 'None (1)'	System	09 Oct 2020 17:12:42
	System	09 Oct 2020 17:12:42

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:37', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a312c2d3-0dd2-4469-82bd-73cdc9d395dd' User entered '09 Oct 2020 12:12'	System	09 Oct 2020 17:12:42
	System	09 Oct 2020 17:12:42

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 3'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:05:35', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ffb8b5a6-480f-4f1d-b6eb-190f34259f30'	System	11 Oct 2020 00:05:48
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 00:05:48

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:05:37', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ffb8b5a6-480f-4f1d-b6eb-190f34259f30'	System	11 Oct 2020 00:05:48
User entered 'No (N)'	System	11 Oct 2020 00:05:48

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:05:40', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ffb8b5a6-480f-4f1d-b6eb-190f34259f30'	System	11 Oct 2020 00:05:48
User entered 'No (N)'	System	11 Oct 2020 00:05:48



US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:05:43', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ffb8b5a6-480f-4f1d-b6eb-190f34259f30'	System	11 Oct 2020 00:05:48
User entered 'None (1)'	System	11 Oct 2020 00:05:48

**US3322302**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:05:45', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ffb8b5a6-480f-4f1d-b6eb-190f34259f30' User entered '10 Oct 2020 19:05'	System	11 Oct 2020 00:05:48
	System	11 Oct 2020 00:05:48

**US3322302**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 4'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:29:38', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'dcf2c8c0-4b0b-4300-ad85-66c4638133f2'	System	11 Oct 2020 20:29:51
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 20:29:51

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:29:42', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'dcf2c8c0-4b0b-4300-ad85-66c4638133f2' User entered 'No (N)'	System	11 Oct 2020 20:29:51
	System	11 Oct 2020 20:29:51

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:29:44', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'dcf2c8c0-4b0b-4300-ad85-66c4638133f2' User entered 'No (N)'	System	11 Oct 2020 20:29:51
	System	11 Oct 2020 20:29:51



US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:29:46', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'dcf2c8c0-4b0b-4300-ad85-66c4638133f2' User entered 'None (1)'	System	11 Oct 2020 20:29:51
	System	11 Oct 2020 20:29:51

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:29:48', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'dcf2c8c0-4b0b-4300-ad85-66c4638133f2' User entered '11 Oct 2020 15:29'	System	11 Oct 2020 20:29:51
	System	11 Oct 2020 20:29:51

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 5'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:35:42', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '73f60eb6-893c-494a-a19e-37097273ae0b'	System	13 Oct 2020 04:35:56
User entered 'Does not interfere with activity (2)'	System	13 Oct 2020 04:35:56

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:35:45', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '73f60eb6-893c-494a-a19e-37097273ae0b' User entered 'No (N)'	System	13 Oct 2020 04:35:56
	System	13 Oct 2020 04:35:56

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:35:47', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '73f60eb6-893c-494a-a19e-37097273ae0b' User entered 'No (N)'	System	13 Oct 2020 04:35:56
	System	13 Oct 2020 04:35:56



US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:35:50', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '73f60eb6-893c-494a-a19e-37097273ae0b' User entered 'None (1)'	System	13 Oct 2020 04:35:56
	System	13 Oct 2020 04:35:56

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:35:53', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '73f60eb6-893c-494a-a19e-37097273ae0b' User entered '12 Oct 2020 23:35'	System	13 Oct 2020 04:35:56
	System	13 Oct 2020 04:35:56

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 6'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:11', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'bf43958d-d47f-45b8-8bbf-437049bde9bf'	System	13 Oct 2020 19:27:20
User entered 'Does not interfere with activity (2)'	System	13 Oct 2020 19:27:20

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:13', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'bf43958d-d47f-45b8-8bbf-437049bde9bf' User entered 'No (N)'	System	13 Oct 2020 19:27:20
	System	13 Oct 2020 19:27:20

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:14', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'bf43958d-d47f-45b8-8bbf-437049bde9bf' User entered 'No (N)'	System	13 Oct 2020 19:27:20
	System	13 Oct 2020 19:27:20



US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:16', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'bf43958d-d47f-45b8-8bbf-437049bde9bf' User entered 'None (1)'	System	13 Oct 2020 19:27:20
	System	13 Oct 2020 19:27:20

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:18', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'bf43958d-d47f-45b8-8bbf-437049bde9bf' User entered '13 Oct 2020 14:27'	System	13 Oct 2020 19:27:20
	System	13 Oct 2020 19:27:20

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 7'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:10', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '59f2611b-69e7-4436-b188-b576978381df' User entered 'Does not interfere with activity (2)'	System	14 Oct 2020 19:47:22
	System	14 Oct 2020 19:47:22

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:13', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '59f2611b-69e7-4436-b188-b576978381df' User entered 'No (N)'	System	14 Oct 2020 19:47:22
	System	14 Oct 2020 19:47:22

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:14', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '59f2611b-69e7-4436-b188-b576978381df' User entered 'No (N)'	System	14 Oct 2020 19:47:22
	System	14 Oct 2020 19:47:22



US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:16', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '59f2611b-69e7-4436-b188-b576978381df' User entered 'None (1)'	System	14 Oct 2020 19:47:22
	System	14 Oct 2020 19:47:22

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:18', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '59f2611b-69e7-4436-b188-b576978381df' User entered '14 Oct 2020 14:47'	System	14 Oct 2020 19:47:22
	System	14 Oct 2020 19:47:22

**US3322302**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

**US3322302**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:36', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a54e5fdc-1218-4bee-87bf-1241bfe66b54' User entered 'None (0)'	System	08 Oct 2020 21:16:58
	System	08 Oct 2020 21:16:58

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:41', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a54e5fdc-1218-4bee-87bf-1241bfe66b54' User entered 'None (0)'	System	08 Oct 2020 21:16:58
	System	08 Oct 2020 21:16:58

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:42', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a54e5fdc-1218-4bee-87bf-1241bfe66b54' User entered 'None (0)'	System	08 Oct 2020 21:16:58
	System	08 Oct 2020 21:16:58



US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:43', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a54e5fdc-1218-4bee-87bf-1241bfe66b54' User entered 'None (0)'	System	08 Oct 2020 21:16:58
	System	08 Oct 2020 21:16:58

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:45', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a54e5fdc-1218-4bee-87bf-1241bfe66b54' User entered 'None (0)'	System	08 Oct 2020 21:16:58
	System	08 Oct 2020 21:16:58

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:46', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a54e5fdc-1218-4bee-87bf-1241bfe66b54' User entered 'None (0)'	System	08 Oct 2020 21:16:58
	System	08 Oct 2020 21:16:58

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:51', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a54e5fdc-1218-4bee-87bf-1241bfe66b54' User entered 'No (N)'	System	08 Oct 2020 21:16:58
	System	08 Oct 2020 21:16:58

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T16:16:53', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'a54e5fdc-1218-4bee-87bf-1241bfe66b54' User entered '08 Oct 2020 16:16'	System	08 Oct 2020 21:16:58
	System	08 Oct 2020 21:16:58

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '08 Oct 2020 16:04'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '08 Oct 2020 18:34'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 1, after vaccination (at home)'	System	08 Oct 2020 20:53:28



US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:37:06', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '72e0f119-488e-4325-b3c3-b3f9239a922b' User entered 'None (0)'	System	09 Oct 2020 00:37:22
	System	09 Oct 2020 00:37:22

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:37:07', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '72e0f119-488e-4325-b3c3-b3f9239a922b' User entered 'None (0)'	System	09 Oct 2020 00:37:22
	System	09 Oct 2020 00:37:22

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:37:09', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '72e0f119-488e-4325-b3c3-b3f9239a922b' User entered 'None (0)'	System	09 Oct 2020 00:37:22
	System	09 Oct 2020 00:37:22

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:37:10', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '72e0f119-488e-4325-b3c3-b3f9239a922b' User entered 'None (0)'	System	09 Oct 2020 00:37:22
	System	09 Oct 2020 00:37:22

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:37:12', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '72e0f119-488e-4325-b3c3-b3f9239a922b' User entered 'None (0)'	System	09 Oct 2020 00:37:22
	System	09 Oct 2020 00:37:22

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:37:13', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '72e0f119-488e-4325-b3c3-b3f9239a922b' User entered 'None (0)'	System	09 Oct 2020 00:37:22
	System	09 Oct 2020 00:37:22

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:37:16', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '72e0f119-488e-4325-b3c3-b3f9239a922b' User entered 'No (N)'	System	09 Oct 2020 00:37:22
	System	09 Oct 2020 00:37:22

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-08T19:37:17', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '72e0f119-488e-4325-b3c3-b3f9239a922b' User entered '08 Oct 2020 19:37'	System	09 Oct 2020 00:37:22
	System	09 Oct 2020 00:37:22



US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '08 Oct 2020 19:29'	System	08 Oct 2020 20:53:28

**US3322302**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 2'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:42', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2599dab6-ceae-421a-bf14-53936ef7741d'	System	09 Oct 2020 17:13:04
User entered 'No interference with activity (1)'	System	09 Oct 2020 17:13:04

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:46', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2599dab6-ceae-421a-bf14-53936ef7741d' User entered 'None (0)'	System	09 Oct 2020 17:13:04
	System	09 Oct 2020 17:13:04

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:48', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2599dab6-ceae-421a-bf14-53936ef7741d' User entered 'None (0)'	System	09 Oct 2020 17:13:04
	System	09 Oct 2020 17:13:04

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:50', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2599dab6-ceae-421a-bf14-53936ef7741d' User entered 'None (0)'	System	09 Oct 2020 17:13:04
	System	09 Oct 2020 17:13:04

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:51', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2599dab6-ceae-421a-bf14-53936ef7741d' User entered 'None (0)'	System	09 Oct 2020 17:13:04
	System	09 Oct 2020 17:13:04



US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:53', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2599dab6-ceae-421a-bf14-53936ef7741d' User entered 'None (0)'	System	09 Oct 2020 17:13:04
	System	09 Oct 2020 17:13:04

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:57', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2599dab6-ceae-421a-bf14-53936ef7741d' User entered 'No (N)'	System	09 Oct 2020 17:13:04
	System	09 Oct 2020 17:13:04

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-09T12:12:59', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2599dab6-ceae-421a-bf14-53936ef7741d' User entered '09 Oct 2020 12:12'	System	09 Oct 2020 17:13:04
	System	09 Oct 2020 17:13:04

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '09 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

**US3322302**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '10 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 3'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:05:49', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9d3db9e8-fd1d-4fe7-886a-f86028542003'	System	11 Oct 2020 00:06:11
User entered 'No interference with activity (1)'	System	11 Oct 2020 00:06:11

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:05:53', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9d3db9e8-fd1d-4fe7-886a-f86028542003' User entered 'None (0)'	System	11 Oct 2020 00:06:11
	System	11 Oct 2020 00:06:11



US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:05:56', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9d3db9e8-fd1d-4fe7-886a-f86028542003' User entered 'None (0)'	System	11 Oct 2020 00:06:11
	System	11 Oct 2020 00:06:11

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:05:58', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9d3db9e8-fd1d-4fe7-886a-f86028542003' User entered 'None (0)'	System	11 Oct 2020 00:06:11
	System	11 Oct 2020 00:06:11

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:06:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9d3db9e8-fd1d-4fe7-886a-f86028542003' User entered 'None (0)'	System	11 Oct 2020 00:06:11
	System	11 Oct 2020 00:06:11

**US3322302**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:07:47**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:06:02', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9d3db9e8-fd1d-4fe7-886a-f86028542003' User entered 'None (0)'	System	11 Oct 2020 00:06:11
	System	11 Oct 2020 00:06:11

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:06:04', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9d3db9e8-fd1d-4fe7-886a-f86028542003' User entered 'No (N)'	System	11 Oct 2020 00:06:11
	System	11 Oct 2020 00:06:11

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-10T19:06:07', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '9d3db9e8-fd1d-4fe7-886a-f86028542003' User entered '10 Oct 2020 19:06'	System	11 Oct 2020 00:06:11
	System	11 Oct 2020 00:06:11

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '10 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

**US3322302**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '11 Oct 2020 11:59'	System	08 Oct 2020 20:53:28



US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 4'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:29:52', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ea439cf1-9a2d-4f59-a2b8-4dee547b22df' User entered 'None (0)'	System	11 Oct 2020 20:30:09
	System	11 Oct 2020 20:30:09

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:29:54', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ea439cf1-9a2d-4f59-a2b8-4dee547b22df' User entered 'None (0)'	System	11 Oct 2020 20:30:09
	System	11 Oct 2020 20:30:09

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:29:56', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ea439cf1-9a2d-4f59-a2b8-4dee547b22df' User entered 'None (0)'	System	11 Oct 2020 20:30:09
	System	11 Oct 2020 20:30:09

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:29:58', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ea439cf1-9a2d-4f59-a2b8-4dee547b22df' User entered 'None (0)'	System	11 Oct 2020 20:30:09
	System	11 Oct 2020 20:30:09

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:30:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ea439cf1-9a2d-4f59-a2b8-4dee547b22df' User entered 'None (0)'	System	11 Oct 2020 20:30:09
	System	11 Oct 2020 20:30:09

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:30:02', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ea439cf1-9a2d-4f59-a2b8-4dee547b22df' User entered 'None (0)'	System	11 Oct 2020 20:30:09
	System	11 Oct 2020 20:30:09

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:30:05', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ea439cf1-9a2d-4f59-a2b8-4dee547b22df' User entered 'No (N)'	System	11 Oct 2020 20:30:09
	System	11 Oct 2020 20:30:09



US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-11T15:30:07', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ea439cf1-9a2d-4f59-a2b8-4dee547b22df' User entered '11 Oct 2020 15:30'	System	11 Oct 2020 20:30:09
	System	11 Oct 2020 20:30:09

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '11 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '12 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 5'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:35:57', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b0cffa27-a17e-4ebc-82a0-c653f9fd16ee' User entered 'None (0)'	System	13 Oct 2020 04:36:13
	System	13 Oct 2020 04:36:13

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:35:58', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b0cffa27-a17e-4ebc-82a0-c653f9fd16ee' User entered 'None (0)'	System	13 Oct 2020 04:36:13
	System	13 Oct 2020 04:36:13

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:36:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b0cffa27-a17e-4ebc-82a0-c653f9fd16ee' User entered 'None (0)'	System	13 Oct 2020 04:36:13
	System	13 Oct 2020 04:36:13

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:36:01', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b0cffa27-a17e-4ebc-82a0-c653f9fd16ee' User entered 'None (0)'	System	13 Oct 2020 04:36:13
	System	13 Oct 2020 04:36:13



US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:36:03', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b0cffa27-a17e-4ebc-82a0-c653f9fd16ee' User entered 'None (0)'	System	13 Oct 2020 04:36:13
	System	13 Oct 2020 04:36:13

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:36:05', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b0cffa27-a17e-4ebc-82a0-c653f9fd16ee' User entered 'None (0)'	System	13 Oct 2020 04:36:13
	System	13 Oct 2020 04:36:13

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:36:08', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b0cffa27-a17e-4ebc-82a0-c653f9fd16ee' User entered 'No (N)'	System	13 Oct 2020 04:36:13
	System	13 Oct 2020 04:36:13

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-12T23:36:10', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b0cffa27-a17e-4ebc-82a0-c653f9fd16ee' User entered '12 Oct 2020 23:36'	System	13 Oct 2020 04:36:13
	System	13 Oct 2020 04:36:13

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '12 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

**US3322302**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '13 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 6'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:22', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '888a949e-2877-4c89-8908-2b6478298b7c' User entered 'None (0)'	System	13 Oct 2020 19:27:39
	System	13 Oct 2020 19:27:39



US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:24', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '888a949e-2877-4c89-8908-2b6478298b7c' User entered 'None (0)'	System	13 Oct 2020 19:27:39
	System	13 Oct 2020 19:27:39

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:25', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '888a949e-2877-4c89-8908-2b6478298b7c' User entered 'None (0)'	System	13 Oct 2020 19:27:39
	System	13 Oct 2020 19:27:39

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:27', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '888a949e-2877-4c89-8908-2b6478298b7c' User entered 'None (0)'	System	13 Oct 2020 19:27:39
	System	13 Oct 2020 19:27:39

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:29', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '888a949e-2877-4c89-8908-2b6478298b7c' User entered 'None (0)'	System	13 Oct 2020 19:27:39
	System	13 Oct 2020 19:27:39

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:30', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '888a949e-2877-4c89-8908-2b6478298b7c' User entered 'None (0)'	System	13 Oct 2020 19:27:39
	System	13 Oct 2020 19:27:39

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:34', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '888a949e-2877-4c89-8908-2b6478298b7c' User entered 'No (N)'	System	13 Oct 2020 19:27:39
	System	13 Oct 2020 19:27:39

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-13T14:27:35', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '888a949e-2877-4c89-8908-2b6478298b7c' User entered '13 Oct 2020 14:27'	System	13 Oct 2020 19:27:39
	System	13 Oct 2020 19:27:39

**US3322302**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '13 Oct 2020 12:00'	System	08 Oct 2020 20:53:28



US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '14 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	08 Oct 2020 20:53:28
User entered 'Day 7'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:21', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4984da4f-b007-4389-8ec4-8931a9504d36' User entered 'None (0)'	System	14 Oct 2020 19:47:39
	System	14 Oct 2020 19:47:39

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:23', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4984da4f-b007-4389-8ec4-8931a9504d36' User entered 'None (0)'	System	14 Oct 2020 19:47:39
	System	14 Oct 2020 19:47:39

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:25', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4984da4f-b007-4389-8ec4-8931a9504d36' User entered 'None (0)'	System	14 Oct 2020 19:47:39
	System	14 Oct 2020 19:47:39

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:26', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4984da4f-b007-4389-8ec4-8931a9504d36' User entered 'None (0)'	System	14 Oct 2020 19:47:39
	System	14 Oct 2020 19:47:39

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:27', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4984da4f-b007-4389-8ec4-8931a9504d36' User entered 'None (0)'	System	14 Oct 2020 19:47:39
	System	14 Oct 2020 19:47:39

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:29', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4984da4f-b007-4389-8ec4-8931a9504d36' User entered 'None (0)'	System	14 Oct 2020 19:47:39
	System	14 Oct 2020 19:47:39



US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:31', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4984da4f-b007-4389-8ec4-8931a9504d36' User entered 'No (N)'	System	14 Oct 2020 19:47:39
	System	14 Oct 2020 19:47:39

US3322302

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-14T14:47:33', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4984da4f-b007-4389-8ec4-8931a9504d36' User entered '14 Oct 2020 14:47'	System	14 Oct 2020 19:47:39
	System	14 Oct 2020 19:47:39

**US3322302**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '14 Oct 2020 12:00'	System	08 Oct 2020 20:53:28

**US3322302**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '15 Oct 2020 11:59'	System	08 Oct 2020 20:53:28

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	13 Oct 2020 19:27:20
User entered 'Day 8'	System	13 Oct 2020 19:27:20

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 17:07:47

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-15T21:38:58', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '804cb6f0-e6ee-4a15-a409-0d65a06f330f' User entered 'None (1)'	System	16 Oct 2020 02:39:03
	System	16 Oct 2020 02:39:03

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 17:07:47

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-15T21:39:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '804cb6f0-e6ee-4a15-a409-0d65a06f330f' User entered '15 Oct 2020 21:39'	System	16 Oct 2020 02:39:03
	System	16 Oct 2020 02:39:03

US3322302

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 19:27:20



US3322302

Folder: Diary Dose 2 (1)

Form: Injection Pain\_Day(8)

Generated On: 09 Jun 2021 17:07:47

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 19:27:20

US3322302

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	13 Oct 2020 19:27:20
User entered 'Day 8'	System	13 Oct 2020 19:27:20

US3322302

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-15T21:39:03', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b5493e3a-eea3-41e7-ab34-707b10681d45' User entered 'No (N)'	System	16 Oct 2020 02:39:10
	System	16 Oct 2020 02:39:10

US3322302

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:07:47

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5634AD45-B3E9-4B18-B925-A2B2EB48F73A)', Time: '2020-10-15T21:39:05', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b5493e3a-eea3-41e7-ab34-707b10681d45' User entered '15 Oct 2020 21:39'	System	16 Oct 2020 02:39:10
	System	16 Oct 2020 02:39:10

US3322302

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 17:07:47

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '15 Oct 2020 12:00'	System	13 Oct 2020 19:27:20

**US3322302**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 09 Jun 2021 17:07:47**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
User entered '16 Oct 2020 11:59'	System	13 Oct 2020 19:27:20

US3322302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:30:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 18:28:59

US3322302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:30:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 07:30:44
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'previous attempts unsuccessful, this was the day contact was made' (Site from System).	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 18:29:18
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Oct 2020 18:28:59
User entered '19 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 18:28:59



US3322302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:30:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 18:28:59

US3322302

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:30:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 18:28:59

US3322302

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:30:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	19 Oct 2020 18:29:22

**US3322302**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:07:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'I'	System	19 Oct 2020 18:29:22

US3322302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:30:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:06:53

US3322302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:30:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '22 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:06:53

US3322302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:30:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:06:53

US3322302

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:30:51
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:06:53



US3322302

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:30:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	22 Oct 2020 17:06:21

US3322302

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'I'	System	22 Oct 2020 17:06:21

US3322302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:31:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 19:27:59

US3322302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:31:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '30 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 19:27:59

US3322302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:31:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 19:27:59

US3322302

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:31:54
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'multiple unsuccessful attempts'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 19:27:59

US3322302

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:32:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 19:27:37

US3322302

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'I'	System	02 Nov 2020 19:27:37



US3322302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:34:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:24:04

US3322302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:34:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '11 Nov 2020'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:24:04

US3322302

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:34:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Clinic (Clinic)'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:24:04

**US3322302**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:07:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'VISIT3'	System	11 Nov 2020 17:24:04

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:24:47

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '11 Nov 2020'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:24:47

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '09:42'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:24:47

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '11 Nov 2020 09:42'	System	11 Nov 2020 17:24:47



US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '97.8' F	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:24:47

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Oral (Oral)'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:24:47

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered empty.	(b) (4)	
	Moez Talpur (b) (4)	11 Nov 2020 17:24:47
	(b) (4)	

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '57'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:24:47

**US3322302**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:07:47**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'bpm'	System	11 Nov 2020 17:24:47

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '16'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:24:47

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'breaths/min'	System	11 Nov 2020 17:24:47

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '113'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:24:47



US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'mmHg'	System	11 Nov 2020 17:24:47

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '76'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:24:47

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'mmHg'	System	11 Nov 2020 17:24:47

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12

US3322302

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12

US3322302

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:24:57

US3322302

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '11 Nov 2020'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:24:57

US3322302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:25:09



US3322302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '11 Nov 2020'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:25:09

US3322302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '10:30'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:25:09

US3322302

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered '11 Nov 2020 10:30'	System	11 Nov 2020 17:25:09

US3322302

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:36:50
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Moez Talpur (b) (4) (b) (4)	11 Nov 2020 17:25:17

**US3322302**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:07:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'I'	System	11 Nov 2020 17:25:17

US3322302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 64'	System	10 Sep 2020 20:57:24

US3322302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

[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)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-11-10T14:55:40', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '16a98fea-a846-43c6-8eed-0832714e8297'	System	10 Nov 2020 20:55:53
User entered 'No (N)'	System	10 Nov 2020 20:55:53

US3322302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-11-10T14:55:46', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '16a98fea-a846-43c6-8eed-0832714e8297'	System	10 Nov 2020 20:55:53
User entered 'No (N)'	System	10 Nov 2020 20:55:53



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-11-10T14:55:50', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '16a98fea-a846-43c6-8eed-0832714e8297' User entered '10 Nov 2020 14:55:50'	System	10 Nov 2020 20:55:53
	System	10 Nov 2020 20:55:53

US3322302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.		
User entered '10 Nov 2020 00:01'	System	10 Sep 2020 20:57:24
	System	10 Sep 2020 20:57:24

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	10 Sep 2020 20:57:24
User entered '14 Nov 2020 23:59'	System	10 Sep 2020 20:57:24

US3322302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	10 Sep 2020 20:57:24
User entered 'Day 71'	System	10 Sep 2020 20:57:24

US3322302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-11-18T20:21:04', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '3e8e61a5-e7bd-42e5-8d28-071bf76c43b8' User entered 'No (N)'	System	19 Nov 2020 02:21:17
	System	19 Nov 2020 02:21:17

US3322302

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-11-18T20:21:07', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '3e8e61a5-e7bd-42e5-8d28-071bf76c43b8' User entered 'No (N)'	System	19 Nov 2020 02:21:17
	System	19 Nov 2020 02:21:17

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-11-18T20:21:12', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '3e8e61a5-e7bd-42e5-8d28-071bf76c43b8' User entered '18 Nov 2020 20:21:12'	System	19 Nov 2020 02:21:17
	System	19 Nov 2020 02:21:17

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	10 Sep 2020 20:57:24
User entered '17 Nov 2020 00:01'	System	10 Sep 2020 20:57:24



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:52:16
Data entry locked.	System	10 Sep 2020 20:57:24
User entered '21 Nov 2020 23:59'	System	10 Sep 2020 20:57:24

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-11-21T14:16:06', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '5e511c10-32ed-4c17-83cd-4aece407d75f'	System	21 Nov 2020 20:16:13
User entered 'No (N)'	System	21 Nov 2020 20:16:13

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-11-21T14:16:08', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '5e511c10-32ed-4c17-83cd-4aece407d75f' User entered 'No (N)'	System	21 Nov 2020 20:16:13

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-11-21T14:16:11', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '5e511c10-32ed-4c17-83cd-4aece407d75f' User entered '21 Nov 2020 14:16:11'	System	21 Nov 2020 20:16:13
	System	21 Nov 2020 20:16:13

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-11-28T18:50:40', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b923f873-98de-405b-bcad-844d94e61dfa' User entered 'No (N)'	System	29 Nov 2020 00:50:52
	System	29 Nov 2020 00:50:52

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-11-28T18:50:45', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b923f873-98de-405b-bcad-844d94e61dfa' User entered 'No (N)'	System	29 Nov 2020 00:50:52
	System	29 Nov 2020 00:50:52

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-11-28T18:50:50', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'b923f873-98de-405b-bcad-844d94e61dfa' User entered '28 Nov 2020 18:50:50'	System	29 Nov 2020 00:50:52
	System	29 Nov 2020 00:50:52

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-12-05T14:27:39', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ea5c7f67-bfbd-4c3c-ad10-b099646bce6e' User entered 'No (N)'	System	05 Dec 2020 20:27:48
	System	05 Dec 2020 20:27:48

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-12-05T14:27:42', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ea5c7f67-bfbd-4c3c-ad10-b099646bce6e'	System	05 Dec 2020 20:27:48
User entered 'No (N)'	System	05 Dec 2020 20:27:48



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-12-05T14:27:45', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ea5c7f67-bfbd-4c3c-ad10-b099646bce6e' User entered '05 Dec 2020 14:27:45'	System	05 Dec 2020 20:27:48
	System	05 Dec 2020 20:27:48

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-12-12T02:16:44', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '8c23dda7-c81c-46b0-bb4c-90da5a960f8e' User entered 'No (N)'	System	12 Dec 2020 08:16:52
	System	12 Dec 2020 08:16:52

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-12-12T02:16:47', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '8c23dda7-c81c-46b0-bb4c-90da5a960f8e' User entered 'No (N)'	System	12 Dec 2020 08:16:52
	System	12 Dec 2020 08:16:52

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-12-12T02:16:50', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '8c23dda7-c81c-46b0-bb4c-90da5a960f8e' User entered '12 Dec 2020 02:16:50'	System	12 Dec 2020 08:16:52
	System	12 Dec 2020 08:16:52

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-12-19T00:08:01', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '0d163fdb-ff10-4bd7-883d-8632b5d1010c' User entered 'No (N)'	System	19 Dec 2020 06:08:10
	System	19 Dec 2020 06:08:10

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-12-19T00:08:04', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '0d163fdb-ff10-4bd7-883d-8632b5d1010c'	System	19 Dec 2020 06:08:10
User entered 'No (N)'	System	19 Dec 2020 06:08:10

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-12-19T00:08:06', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '0d163fdb-ff10-4bd7-883d-8632b5d1010c' User entered '19 Dec 2020 00:08:06'	System	19 Dec 2020 06:08:10
	System	19 Dec 2020 06:08:10

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-12-26T06:48:40', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f9829983-f402-4b87-826d-850a8b25b0a1' User entered 'No (N)'	System	26 Dec 2020 12:48:49
	System	26 Dec 2020 12:48:49

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-12-26T06:48:43', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f9829983-f402-4b87-826d-850a8b25b0a1' User entered 'No (N)'	System	26 Dec 2020 12:48:49
	System	26 Dec 2020 12:48:49

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2020-12-26T06:48:46', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f9829983-f402-4b87-826d-850a8b25b0a1' User entered '26 Dec 2020 06:48:46'	System	26 Dec 2020 12:48:49
	System	26 Dec 2020 12:48:49

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-02T17:23:02', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '6165cbe9-2c16-4601-ad74-6eadf890936a' User entered 'No (N)'	System	02 Jan 2021 23:23:09
	System	02 Jan 2021 23:23:09

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-02T17:23:03', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '6165cbe9-2c16-4601-ad74-6eadf890936a' User entered 'No (N)'	System	02 Jan 2021 23:23:09
	System	02 Jan 2021 23:23:09



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-02T17:23:05', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '6165cbe9-2c16-4601-ad74-6eadf890936a' User entered '02 Jan 2021 17:23:05'	System	02 Jan 2021 23:23:09
	System	02 Jan 2021 23:23:09

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-11T12:25:44', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4f379a01-1530-4e56-9c7d-68995ab53351' User entered 'No (N)'	System	11 Jan 2021 18:25:52
	System	11 Jan 2021 18:25:52

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-11T12:25:46', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4f379a01-1530-4e56-9c7d-68995ab53351' User entered 'No (N)'	System	11 Jan 2021 18:25:52

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-11T12:25:49', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '4f379a01-1530-4e56-9c7d-68995ab53351' User entered '11 Jan 2021 12:25:49'	System	11 Jan 2021 18:25:52
	System	11 Jan 2021 18:25:52

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-16T00:01:51', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2e355557-9b3a-4ee2-9c6d-44f687fb5ee0'	System	16 Jan 2021 06:02:45
User entered 'No (N)'	System	16 Jan 2021 06:02:45

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-16T00:01:56', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2e355557-9b3a-4ee2-9c6d-44f687fb5ee0'	System	16 Jan 2021 06:02:45
User entered 'No (N)'	System	16 Jan 2021 06:02:45

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-16T00:01:59', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2e355557-9b3a-4ee2-9c6d-44f687fb5ee0' User entered '16 Jan 2021 00:01:59'	System	16 Jan 2021 06:02:45
	System	16 Jan 2021 06:02:45

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-25T12:00:36', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '616d50a4-20e3-4acf-878c-4c490811e474'	System	25 Jan 2021 18:01:11
User entered 'No (N)'	System	25 Jan 2021 18:01:11

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-25T12:00:39', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '616d50a4-20e3-4acf-878c-4c490811e474'	System	25 Jan 2021 18:01:11
User entered 'No (N)'	System	25 Jan 2021 18:01:11

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-25T12:00:41', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '616d50a4-20e3-4acf-878c-4c490811e474' User entered '25 Jan 2021 12:00:41'	System	25 Jan 2021 18:01:11
	System	25 Jan 2021 18:01:11

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-30T07:16:37', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '75b59bce-2012-40b1-b9be-b5d324cdcaf1' User entered 'No (N)'	System	30 Jan 2021 13:16:49
	System	30 Jan 2021 13:16:49

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-30T07:16:41', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '75b59bce-2012-40b1-b9be-b5d324cdcaf1' User entered 'No (N)'	System	30 Jan 2021 13:16:49
	System	30 Jan 2021 13:16:49



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-01-30T07:16:44', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '75b59bce-2012-40b1-b9be-b5d324cdcaf1' User entered '30 Jan 2021 07:16:44'	System	30 Jan 2021 13:16:49
	System	30 Jan 2021 13:16:49

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-02-06T08:02:31', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f84c5e20-321d-4b53-a1e0-f6fa74a56a02'	System	06 Feb 2021 14:02:43
User entered 'No (N)'	System	06 Feb 2021 14:02:43

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-02-06T08:02:34', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f84c5e20-321d-4b53-a1e0-f6fa74a56a02'	System	06 Feb 2021 14:02:43
User entered 'No (N)'	System	06 Feb 2021 14:02:43

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-02-06T08:02:39', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f84c5e20-321d-4b53-a1e0-f6fa74a56a02' User entered '06 Feb 2021 08:02:39'	System	06 Feb 2021 14:02:43
	System	06 Feb 2021 14:02:43

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-02-13T07:22:08', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '3592a69d-bbcf-4547-a54e-8fb2152fafd8' User entered 'No (N)'	System	13 Feb 2021 13:22:16
	System	13 Feb 2021 13:22:16

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-02-13T07:22:11', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '3592a69d-bbcf-4547-a54e-8fb2152fafd8' User entered 'No (N)'	System	13 Feb 2021 13:22:16
	System	13 Feb 2021 13:22:16

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-02-13T07:22:13', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '3592a69d-bbcf-4547-a54e-8fb2152fafd8'	System	13 Feb 2021 13:22:16
User entered '13 Feb 2021 07:22:13'	System	13 Feb 2021 13:22:16

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-02-20T07:26:16', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '36220897-545a-4108-8190-94f267584830'	System	20 Feb 2021 13:26:25
User entered 'No (N)'	System	20 Feb 2021 13:26:25

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-02-20T07:26:18', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '36220897-545a-4108-8190-94f267584830' User entered 'No (N)'	System	20 Feb 2021 13:26:25

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-02-20T07:26:20', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '36220897-545a-4108-8190-94f267584830' User entered '20 Feb 2021 07:26:20'	System	20 Feb 2021 13:26:25
	System	20 Feb 2021 13:26:25

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-01T12:01:20-06:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '3ee319bf-927c-478a-b063-8bcf6d617c45'	System	01 Mar 2021 18:05:52
User entered 'No (N)'	System	01 Mar 2021 18:05:52

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-01T12:01:22-06:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '3ee319bf-927c-478a-b063-8bcf6d617c45'	System	01 Mar 2021 18:05:52
User entered 'No (N)'	System	01 Mar 2021 18:05:52



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-01T12:01:25-06:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '3ee319bf-927c-478a-b063-8bcf6d617c45'	System	01 Mar 2021 18:05:52
User entered '01 Mar 2021 12:01:25'	System	01 Mar 2021 18:05:52

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-06T08:22:35-06:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2e26e997-fb05-4740-99cb-177bf5f8663a'	System	06 Mar 2021 14:22:47
User entered 'No (N)'	System	06 Mar 2021 14:22:47

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-06T08:22:38-06:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2e26e997-fb05-4740-99cb-177bf5f8663a'	System	06 Mar 2021 14:22:47
User entered 'No (N)'	System	06 Mar 2021 14:22:47

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-06T08:22:41-06:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2e26e997-fb05-4740-99cb-177bf5f8663a' User entered '06 Mar 2021 08:22:41'	System	06 Mar 2021 14:22:47
	System	06 Mar 2021 14:22:47

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-13T07:49:01-06:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ea202c8e-a1bc-46d5-a6f9-215272310d2b'	System	13 Mar 2021 13:49:09
User entered 'No (N)'	System	13 Mar 2021 13:49:09

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-13T07:49:04-06:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ea202c8e-a1bc-46d5-a6f9-215272310d2b'	System	13 Mar 2021 13:49:09
User entered 'No (N)'	System	13 Mar 2021 13:49:09

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-13T07:49:06-06:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'ea202c8e-a1bc-46d5-a6f9-215272310d2b'	System	13 Mar 2021 13:49:09
User entered '13 Mar 2021 07:49:06'	System	13 Mar 2021 13:49:09

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-20T08:42:36-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'eafa965d-b940-4f79-8ced-4e3ce9af0177'	System	20 Mar 2021 13:42:45
User entered 'No (N)'	System	20 Mar 2021 13:42:45

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-20T08:42:39-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'eafa965d-b940-4f79-8ced-4e3ce9af0177'	System	20 Mar 2021 13:42:45
User entered 'No (N)'	System	20 Mar 2021 13:42:45

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-20T08:42:42-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'eafa965d-b940-4f79-8ced-4e3ce9af0177'	System	20 Mar 2021 13:42:45
User entered '20 Mar 2021 08:42:42'	System	20 Mar 2021 13:42:45

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-27T00:04:13-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '7ffebee0-f83d-409c-a41b-0dbafcd67a7'	System	27 Mar 2021 05:04:25
User entered 'No (N)'	System	27 Mar 2021 05:04:25

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-27T00:04:15-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '7ffebee0-f83d-409c-a41b-0dbafcd67a7'	System	27 Mar 2021 05:04:25
User entered 'No (N)'	System	27 Mar 2021 05:04:25



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-27T00:04:17-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '7ffebee0-f83d-409c-a41b-0dbafcda67a7'	System	27 Mar 2021 05:04:25
User entered '27 Mar 2021 00:04:17'	System	27 Mar 2021 05:04:25

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-04-03T06:27:43-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f3c56cae-27d5-46e1-af92-429f8a16486d' User entered 'No (N)'	System	03 Apr 2021 11:27:53
	System	03 Apr 2021 11:27:53

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-04-03T06:27:46-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f3c56cae-27d5-46e1-af92-429f8a16486d'	System	03 Apr 2021 11:27:53
User entered 'No (N)'	System	03 Apr 2021 11:27:53

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-04-03T06:27:48-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'f3c56cae-27d5-46e1-af92-429f8a16486d' User entered '03 Apr 2021 06:27:48'	System	03 Apr 2021 11:27:53
	System	03 Apr 2021 11:27:53

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-04-10T08:27:33-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'd7c156b0-dcf4-4e7a-9fe6-45e8a3266a9c'	System	10 Apr 2021 13:27:39
User entered 'No (N)'	System	10 Apr 2021 13:27:39

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-04-10T08:27:35-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'd7c156b0-dcf4-4e7a-9fe6-45e8a3266a9c'	System	10 Apr 2021 13:27:39
User entered 'No (N)'	System	10 Apr 2021 13:27:39

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-04-10T08:27:37-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: 'd7c156b0-dcf4-4e7a-9fe6-45e8a3266a9c'	System	10 Apr 2021 13:27:39
User entered '10 Apr 2021 08:27:37'	System	10 Apr 2021 13:27:39

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-04-18T10:29:14-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2fdf4f28-0cb2-4411-b162-c0c78340211f' User entered 'No (N)'	System	18 Apr 2021 15:29:22
	System	18 Apr 2021 15:29:22

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-04-18T10:29:16-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2fdf4f28-0cb2-4411-b162-c0c78340211f' User entered 'No (N)'	System	18 Apr 2021 15:29:22
	System	18 Apr 2021 15:29:22

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-04-18T10:29:18-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '2fdf4f28-0cb2-4411-b162-c0c78340211f' User entered '18 Apr 2021 10:29:18'	System	18 Apr 2021 15:29:22
	System	18 Apr 2021 15:29:22

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-04-24T08:11:39-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '221ac870-b493-48de-8c29-caac4a611831' User entered 'No (N)'	System	24 Apr 2021 13:11:46
	System	24 Apr 2021 13:11:46

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-04-24T08:11:41-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '221ac870-b493-48de-8c29-caac4a611831' User entered 'No (N)'	System	24 Apr 2021 13:11:46
	System	24 Apr 2021 13:11:46



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-04-24T08:11:43-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '221ac870-b493-48de-8c29-caac4a611831'	System	24 Apr 2021 13:11:46
User entered '24 Apr 2021 08:11:43'	System	24 Apr 2021 13:11:46

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-05-03T18:18:10-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '694a7716-c434-4b48-9bd3-962ae7e822cf' User entered 'No (N)'	System	03 May 2021 23:18:21
	System	03 May 2021 23:18:21

US3322302

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:07:47

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 (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-05-03T18:18:13-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '694a7716-c434-4b48-9bd3-962ae7e822cf' User entered 'No (N)'	System	03 May 2021 23:18:21
	System	03 May 2021 23:18:21

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-05-03T18:18:16-05:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '694a7716-c434-4b48-9bd3-962ae7e822cf' User entered '03 May 2021 18:18:16'	System	03 May 2021 23:18:21
	System	03 May 2021 23:18:21

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 07:17:14



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 07:17:14

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 07:17:14



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 07:17:14

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 07:17:14

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 07:17:14



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 07:17:14

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 07:17:14

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 07:17:14

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 07:17:14

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 07:17:14



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

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**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 07:17:14



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 07:17:14



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 07:17:14



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 07:17:14



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 07:17:14



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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 07:17:14

**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 07:17:14



**US3322302**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:07:47**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 07:17:14
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 07:17:14

US3322302

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:07:47

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)	25 Apr 2021 19:17:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-01T12:01:30-06:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '83fbaaa7-10ad-4e39-bd57-7941e86bb2eb'	System	01 Mar 2021 18:06:37
User entered 'No (N)'	System	01 Mar 2021 18:06:37

**US3322302**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:17:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B66F23C9-2B96-4316-AECB-C9C57DD0FED9)', Time: '2021-03-01T12:01:33-06:00', User OID: 'PatientReportedOutcome (US3322302)', ODM File OID: '83fbaaa7-10ad-4e39-bd57-7941e86bb2eb' User entered '01 Mar 2021 12:01:33'	System	01 Mar 2021 18:06:37
	System	01 Mar 2021 18:06:37

US3322302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:37:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Dec 2020 21:01:16

US3322302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:37:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '02 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Dec 2020 21:01:16

US3322302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:37:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Dec 2020 21:01:16

US3322302

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:37:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Dec 2020 21:01:16

US3322302

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
DataPoint Verified.		03 Mar 2021 19:37:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	02 Dec 2020 21:01:09



**US3322302**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:07:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:28:12
User entered 'I'	System	02 Dec 2020 21:01:09

US3322302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:50
DataPoint Verified.		03 Mar 2021 19:38:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Jan 2021 22:06:42

US3322302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:50
DataPoint Verified.		03 Mar 2021 19:38:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '05 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Jan 2021 22:06:42

US3322302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:50
DataPoint Verified.		03 Mar 2021 19:38:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Jan 2021 22:06:42

US3322302

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:50
DataPoint Verified.		03 Mar 2021 19:38:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Jan 2021 22:06:42

US3322302

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:50
DataPoint Verified.		03 Mar 2021 19:39:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	06 Jan 2021 22:06:47

**US3322302**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:07:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:50
User entered 'I'	System	06 Jan 2021 22:06:47

US3322302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:50
DataPoint Verified.		03 Mar 2021 19:39:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:15:29



US3322302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:50
DataPoint Verified.		03 Mar 2021 19:39:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '03 Feb 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:15:29

US3322302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:50
DataPoint Verified.		03 Mar 2021 19:39:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:15:29

US3322302

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:50
DataPoint Verified.		03 Mar 2021 19:39:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:15:29

US3322302

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:50
DataPoint Verified.		03 Mar 2021 19:39:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:15:19

**US3322302**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:07:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:38:50
User entered 'I'	System	03 Feb 2021 22:15:19

US3322302

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:41:34
DataPoint Verified.		19 Apr 2021 14:49:17
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:06:56
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:38:38

US3322302

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:41:34
DataPoint Verified.		19 Apr 2021 14:49:17
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:06:56
User entered '05 Mar 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:38:38

US3322302

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:41:34
DataPoint Verified.		19 Apr 2021 14:49:17
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:06:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:38:38



US3322302

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:07:47

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:41:34
DataPoint Verified.		19 Apr 2021 14:49:17
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:06:56
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:38:38

US3322302

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:41:34
DataPoint Verified.		19 Apr 2021 14:50:35
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:06:56
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 19:38:43

**US3322302**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:07:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:41:34
User entered 'I'	System	10 Mar 2021 19:38:43

US3322302

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:52:54
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:37:52

US3322302

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:52:54
User entered '01 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:37:52

US3322302

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:52:54
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:37:52

**US3322302**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:07:47**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	01 Apr 2021 15:37:52

US3322302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:19
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:37:58



US3322302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:37:58

US3322302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:37:58

**US3322302**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:07:47**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:37:58

US3322302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:37:58

US3322302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:37:58

US3322302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:37:58

US3322302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:37:58

**US3322302**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:07:47**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:37:58



US3322302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:37:58

US3322302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:37:58

US3322302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:37:58

**US3322302**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:07:47**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:37:58

US3322302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:37:58

US3322302

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:07:47

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:37:58

US3322302

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:47

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:36
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:38:01

US3322302

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:07:47

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:36
User entered empty.	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:38:01



US3322302

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:57
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:38:08

US3322302

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:57
User entered '01 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:38:08

US3322302

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:54:57
User entered '09:36'	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:38:08

**US3322302**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:07:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '01 Apr 2021 09:36'	System	01 Apr 2021 15:38:08

US3322302

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:07:47

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:32:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 14:55:01
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	01 Apr 2021 15:38:12

**US3322302**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:07:47**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 15:38:12

**US3322302**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:07:47**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 20:54:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:01:21

US3322302

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

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 20:54:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '26 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:01:21



US3322302

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

Form: Visit Date

Generated On: 09 Jun 2021 17:07:47

[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 10:43:30
DataPoint Verified.		03 Mar 2021 20:54:53
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'Clinic (Clinic)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:01:21

**US3322302**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:07:47**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered 'UNBLND_DECIDE'	System	26 Jan 2021 15:01:21

US3322302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:47

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 20:55:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '26 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:02:30

**US3322302**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:07:47**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:06:56
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:48:23

US3322302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:47

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 20:55:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:02:30

**US3322302**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:07:47**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:06:56
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:48:23

US3322302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:47

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 20:55:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '26 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:02:30

US3322302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:47

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 20:55:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:02:30



US3322302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:47

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 20:55:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:02:30

US3322302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:47

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 20:55:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:02:30

US3322302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:47

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 20:55:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:02:30

US3322302

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

Form: Unblinding

Generated On: 09 Jun 2021 17:07:47

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered empty.	System	26 Jan 2021 15:02:30

**US3322302**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:07:47**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered empty.	System	26 Jan 2021 15:02:30

US3322302

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 21:01:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:05:38

US3322302

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 21:01:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '26 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:05:38

US3322302

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:07:47

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 21:01:01
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '08:36' reason for change: Data Entry Error	(b) (4)	
	Elisa Moralez (b) (4)	26 Jan 2021 15:06:35
	(b) (4)	
User entered '08:31'	Elisa Moralez (b) (4)	26 Jan 2021 15:05:38
	(b) (4)	



**US3322302**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:07:47**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '26 Jan 2021 08:36'	System	26 Jan 2021 15:06:35
User entered '26 Jan 2021 08:31'	System	26 Jan 2021 15:05:38

US3322302

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:07:47

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 21:01:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:06:10

US3322302

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:07:47

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 21:01:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '26 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:06:10

US3322302

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:07:47

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
DataPoint Verified.		03 Mar 2021 21:01:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '08:31'	(b) (4) Elisa Moralez (b) (4) (b) (4)	26 Jan 2021 15:06:10

**US3322302**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:07:47**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:43:30
User entered '26 Jan 2021 08:31'	System	26 Jan 2021 15:06:10

US3322302

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:07:47

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:29
DataPoint Verified.		03 Mar 2021 20:21:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:42:29

**US3322302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:07:47**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:44
User entered 'USA-US060-2020-mRNA-1273-P301000009'	System	12 Nov 2020 16:23:40
User entered 'New'	(b) (4), (b) (6)	12 Nov 2020 16:23:40

US3322302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Wrist fracture, LLT: Fractured scaphoid - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 22:35:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Nov 2020 22:35:36
Data point term sent to Coder	System	11 Nov 2020 19:44:49
User entered 'Right Scaphoid Fracture'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53



**US3322302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

US3322302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '22 Oct 2020'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

**US3322302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

**US3322302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:07:47**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Nov 2020 19:43:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)' reason for change: New Information	Frances Saubon (b) (4)	24 Dec 2020 02:54:00
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 15:05:21
DataPoint Un-verified.		03 Mar 2021 19:58:15
DataPoint Verified.		03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '10 Dec 2020' reason for change: New Information	(b) (4) Frances Saubon (b) (4)	24 Dec 2020 02:54:00
User entered empty.	(b) (4) Elisa Moralez (b) (4)	11 Nov 2020 19:43:53



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:07:47**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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)	30 Dec 2020 12:32:13
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).		20 Nov 2020 16:38:12
User entered empty.	System	11 Nov 2020 19:43:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Grade 3/Severe (Grade 3/Severe)'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

US3322302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4) System	11 Nov 2020 19:44:48
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	11 Nov 2020 19:43:53
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:43:53

**US3322302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '0'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

**US3322302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '0'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

US3322302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
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)	11 Nov 2020 19:44:28
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	11 Nov 2020 19:44:28
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	11 Nov 2020 19:43:53
User entered '0'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

US3322302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty; reason for change Data Entry Error	Elisa Moralez (b) (4)	11 Nov 2020 19:44:28
User entered 'No (N)'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

US3322302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '0'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

US3322302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '0'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

US3322302

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '1' reason for change: New Information	Elisa Moralez (b) (4)	11 Nov 2020 19:44:48
User entered '0'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53



**US3322302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:07:47**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '0'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'I'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '1' reason for change: New Information	Elisa Moralez (b) (4)	02 Dec 2020 14:20:20
User entered '0'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User closed query 'PV Query: Please leave query open until resolution is attained. Please provide the final event outcome, when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:43:14
Comment added 'Please see updated log. Stop date has been added'.	Frances Saubon (b) (4)	24 Dec 2020 02:54:23
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Frances Saubon (b) (4)	24 Dec 2020 02:54:00
Query 'PV Query: Please leave query open until resolution is attained. Please provide the final event outcome, when available.' answered with 'per source, pending response from subject on tendonitis stop date, data will be updated as soon as it is available' (Site from Safety).	Frances Saubon (b) (4)	23 Dec 2020 16:13:41
User opened query 'PV Query: Please leave query open until resolution is attained. Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 20:59:46
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)	21 Dec 2020 15:33:37
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 'per source, pending response from subject on tendonitis stop date, data will be updated as soon as it is available' (Site from Safety).	Frances Saubon (b) (4)	18 Dec 2020 03:02:33
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)	14 Dec 2020 17:39:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Outcome](#)

Audit	User	Time (GMT)
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)	10 Dec 2020 16:03:25
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 'Per source, subject clarified that cast was removed on 12-NOV-2020, and subject is currently utilizing a removable split. Subject will inform site when he discontinues use of the removable splint. Data will be updated once more information is available. ' (Site from Safety).	Frances Saubon (b) (4)	09 Dec 2020 21:03:34
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)	08 Dec 2020 18:25:10
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)	07 Dec 2020 15:35:25
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 'Noted; Pending medical records' (Site from Safety).	Frances Saubon (b) (4)	04 Dec 2020 14:23:36
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)	03 Dec 2020 21:46:03
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)	01 Dec 2020 13:07:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Outcome](#)

Audit	User	Time (GMT)
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 'Per source, subject was contacted 23-Nov-2020 and informed site that "everything is good and normal", subject stated that his cast has been removed and he is currently using a removable splint for 4 weeks. Informed subject to contact site if he has any changes.' (Site from Safety).	Frances Saubon (b) (4)	30 Nov 2020 14:39:21
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 16:35:40
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	11 Nov 2020 19:43:53



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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 19:58:09
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User closed query 'PV Query: please include tendonitis in the medical history ecrf.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:07:21
Comment added 'please review updated Medhx, thank you'.	Frances Saubon (b) (4)	07 Dec 2020 18:55:42
Query 'PV Query: please include tendonitis in the medical history ecrf.' answered with 'Noted, awaiting subject's reply regarding stop date.' (Site from Safety).	Frances Saubon (b) (4)	07 Dec 2020 18:25:15
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	07 Dec 2020 15:35:27
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Noted; Pending medical records' (Site from Safety).	Frances Saubon (b) (4)	04 Dec 2020 14:23:47
User opened query 'PV Query: please include tendonitis in the medical history ecrf.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 21:50:01
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 21:49:02
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)	03 Dec 2020 17:16:22
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 17:16:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Narrative](#)

Audit	User	Time (GMT)
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 'per source subject clarified that cast was removed on 12-NOV-2020, and subject is currently utilizing a removable split. Subject will inform site when he discontinues use of the removable splint, and then end date will be updated' (Site from Safety).	Frances Saubon (b) (4)	02 Dec 2020 19:22:23
Query 'PV Query: Please provide the results of any COVID-19 testing performed, including date of collection and type of testing. If not done, please state so. ' answered with 'please see updated concomitant procedures, patient had Covid-19 test and results were negative' (Site from Safety).	Frances Saubon (b) (4)	02 Dec 2020 19:20:44
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 15:15:04
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' answered with 'Pending medical records and site will update appropriately' (Site from Safety).	Frances Saubon (b) (4)	01 Dec 2020 18:57:52
User closed query 'PV Query: Please clarify the clinical context of the event. Was there a preceding fall or accident? Did the subject have any relevant medical history prone to bone fractures? ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 18:08:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please clarify the clinical context of the event. Was there a preceding fall or accident? Did the subject have any relevant medical history prone to bone fractures? ' answered with 'per source, Subject stated that he plays tennis, and has a history of tendonitis in the right arm. Subject had a right wrist pain 17-OCT-2020 then saw an orthopedic surgeon at an outpatient clinic on 22-OCT-2020, X-ray at the clinic reflected subject had a right scaphoid fracture. Subject right scaphoid surgery was on 28-OCT-2020. Subject did not take any medication from time of injury 17-OCT-2020 to surgery on 28-OCT-2020. Subject was prescribed doxycycline 100mg from 28-OCT-2020 through 30-OCT-2020, and Hydrocodone/acetaminophen (Norco) 10mg/325mg from 28-OCT-2020 through 29-OCT-2020 for post-operative wrist pain.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	23 Nov 2020 14:44:42
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 16:36:22
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed, including date of collection and type of testing. If no done, please state so. ' (Site from Safety).		20 Nov 2020 16:36:04
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable' (Site from Safety).		20 Nov 2020 16:35:27
User opened query 'PV Query: Please clarify the clinical context of the event. Was there a preceding fall or accident? Did the subject have any relevant medical history prone to bone fractures? ' (Site from Safety).		20 Nov 2020 16:35:07
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Nov 2020 19:45:19
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	11 Nov 2020 19:45:19

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:07:47

[Narrative](#)

Audit	User	Time (GMT)
User entered 'n/a' reason for change: New Information	Elisa Moralez (b) (4)	11 Nov 2020 19:45:19
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4) System	11 Nov 2020 19:43:53
User entered empty.	Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:43:53

**US3322302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 19:43:53

**US3322302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Nov 2020 19:43:53

**US3322302**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:07:47**

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

Audit	User	Time (GMT)
User entered '0'	System	11 Nov 2020 19:43:53

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 17:07:47**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:29
DataPoint Verified.		03 Mar 2021 19:58:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 22:13:41



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 22:19:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 22:19:45
Data point term sent to Coder Coding entries removed.	System Elisa Moralez (b) (4)	09 Dec 2020 22:18:31 09 Dec 2020 22:17:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 17:46:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 17:46:49
Data point term sent to Coder User entered 'Zyrtec'	System Elisa Moralez (b) (4)	26 Sep 2020 17:45:50 26 Sep 2020 17:45:17

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User closed query 'Per DM CLR: Prophylaxis = Yes; however, please confirm if this Con Med is being given for MH #1. If yes, please update Con Med indication to match with MH #1 as appropriate. Update prophylaxis field response if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:17:18
Query 'Per DM CLR: Prophylaxis = Yes; however, please confirm if this Con Med is being given for MH #1. If yes, please update Con Med indication to match with MH #1 as appropriate. Update prophylaxis field response if applicable. ' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 19:20:25
User entered 'No (N)' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 19:20:16
User opened query 'Per DM CLR: Prophylaxis = Yes; however, please confirm if this Con Med is being given for MH #1. If yes, please update Con Med indication to match with MH #1 as appropriate. Update prophylaxis field response if applicable. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:18:45
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 17:45:17

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User closed query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:17:54
Query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' answered with 'done' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	09 Dec 2020 22:18:06
User entered 'seasonal ALLERGIES' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	09 Dec 2020 22:17:59
User opened query 'Per DM CLR: Please specify the type of allergies (seasonal, medication, food, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate matche.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:04:21
User entered 'allergies'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 17:45:17

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '10'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:17

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'mg (mg)'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:47

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:45:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'as needed (PRN)'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:17

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:47

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:45:17



**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:45:17

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'un UNK 2000'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:17

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '0'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:17

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:17

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:45:17

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:07:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:17

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 17:45:17



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 17:45:17

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 17:45:17

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Sep 2020 17:46:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 17:46:49
Data point term sent to Coder	System	26 Sep 2020 17:45:49
User entered 'Escitalopram'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Depression'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '20'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'mg (mg)'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:47

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'once daily (QD)'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:47

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46

**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:07:47**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'un UNK 2017'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '0'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46

**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:07:47**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:07:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	Elisa Moralez (b) (4)	26 Sep 2020 17:45:46

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:07:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 17:45:46

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 17:45:46

**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 17:45:46

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Sep 2020 17:47:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 17:47:51
Data point term sent to Coder	System	26 Sep 2020 17:46:51
User entered 'Bupropion'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 17:46:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'depression'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:28

**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:07:47**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '150'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:28



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'mg (mg)'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:47

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:46:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'once daily (QD)'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:47

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:46:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:46:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'un UNK 2017'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '0'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:28



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:46:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:07:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:00:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:28

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:07:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 17:46:28

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 17:46:28

**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 17:46:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 17:48:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 17:48:41
Data point term sent to Coder	System	26 Sep 2020 17:47:51
User entered 'Multivitamin'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:58

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:58



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'General Health'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:58

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User closed query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this multivitamin. Please confirm if it can be more appropriately recorded as dose=1, dose unit=tablet as there are multiple component present in this Con Med. Update dose with the corresponding dose unit as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:17:04
User entered '1' reason for change: New Information	Elisa Moralez (b) (4)	02 Nov 2020 20:00:33
Query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this multivitamin. Please confirm if it can be more appropriately recorded as dose=1, dose unit=tablet as there are multiple component present in this Con Med. Update dose with the corresponding dose unit as appropriate. ' answered with 'patient does not know' (Site from DM).	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 19:21:20
User opened query 'Per DM CLR: Please review the dose recorded as this is not the usual dose for this multivitamin. Please confirm if it can be more appropriately recorded as dose=1, dose unit=tablet as there are multiple component present in this Con Med. Update dose with the corresponding dose unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:18:36
User entered '1 pill'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 17:46:58

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'tablet (TABLET)' reason for change:	(b) (4)	
New Information	Elisa Moralez (b) (4)	02 Nov 2020 20:00:33
User entered 'mg (mg)'	(b) (4)	
	Elisa Moralez (b) (4)	26 Sep 2020 17:46:58
	(b) (4)	

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:46:58

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'once daily (QD)'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:58

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:46:58

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:58

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:46:58



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'un UNK 2015'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:58

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '0'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:58

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:58

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:46:58

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:07:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	Elisa Moralez (b) (4)	26 Sep 2020 17:46:58

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:07:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 17:46:58

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 17:46:58

**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 17:46:58



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:47

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
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: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 17:48:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Sep 2020 17:48:41
Data point term sent to Coder	System	26 Sep 2020 17:47:51
User entered 'Famotidine'	Elisa Moralez (b) (4)	26 Sep 2020 17:47:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:47

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User closed query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication and used within the same timeframe. Please update response to "No" if applicable. Otherwise, provide comment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 19:16:52
Query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication and used within the same timeframe. Please update response to "No" if applicable. Otherwise, provide comment. ' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 19:21:36
User entered 'No (N)' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	30 Oct 2020 19:21:30
User opened query 'Per DM CLR: Prophylaxis = Yes; however, please review response as there is an MH recorded that matches this Con Med indication and used within the same timeframe. Please update response to "No" if applicable. Otherwise, provide comment. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 10:18:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	26 Sep 2020 17:47:28

**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:07:47**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'acid reflux'	Elisa Moralez (b) (4)	26 Sep 2020 17:47:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:47

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '40'	Elisa Moralez (b) (4)	26 Sep 2020 17:47:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:47

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'mg (mg)'	Elisa Moralez (b) (4)	26 Sep 2020 17:47:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:47

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:47:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:47

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'once daily (QD)'	Elisa Moralez (b) (4)	26 Sep 2020 17:47:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:47

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:47:28



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:47

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4)	26 Sep 2020 17:47:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:47

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:47:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'un UNK 2017'	Elisa Moralez (b) (4)	26 Sep 2020 17:47:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '0'	Elisa Moralez (b) (4)	26 Sep 2020 17:47:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:47

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	26 Sep 2020 17:47:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	26 Sep 2020 17:47:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:07:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:30
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	Elisa Moralez (b) (4)	26 Sep 2020 17:47:28

**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:07:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 17:47:28



US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Sep 2020 17:47:28

**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Sep 2020 17:47:28

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
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.	(b) (4) Coder Import (b) (4) (b) (4)	11 Nov 2020 19:47:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 19:47:35
Data point term sent to Coder	System	11 Nov 2020 19:46:51
User entered 'Ibuprofen'	Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:46:14

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:46:14

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE AND INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE AND INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 20:18:06
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the HEADACHE AND INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE AND INJECTION SITE PAIN did not meet the AE reporting criteria.' answered with 'this did not constitute an AE, it did not meet the above mentioned criteria' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	09 Dec 2020 21:51:22

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

[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 timeframe. If the HEADACHE AND INJECTION SITE PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE AND INJECTION SITE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:04:36
User entered 'Headache and injection site pain'	Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:46:14

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '400'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:46:14

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'mg (mg)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:46:14



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:46:14

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	12 Nov 2020 14:31:53
	System	12 Nov 2020 14:31:53
User entered 'once daily (QD)' reason for change: New Information	Elisa Moralez (b) (4)	12 Nov 2020 14:31:53
	(b) (4)	
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	11 Nov 2020 19:46:14
User entered 'once (ONCE)'	Elisa Moralez (b) (4)	11 Nov 2020 19:46:14
	(b) (4)	

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:46:14

**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:07:47**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Oral (ORAL)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:46:14

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:46:14

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '08 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:46:14

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:46:14

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:46:14



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '09 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:46:14

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:07:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
DataPoint Verified.		03 Mar 2021 20:17:26
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:46:14

**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:07:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
User entered '1'	System	12 Nov 2020 14:31:53
User entered empty.	System	11 Nov 2020 19:46:14

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
User entered '1'	System	12 Nov 2020 14:31:53
User entered empty.	System	11 Nov 2020 19:46:14

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:41:55
User entered '804 (804)'	System	12 Nov 2020 14:31:53
User entered empty.	System	11 Nov 2020 19:46:14

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:47

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 21:51:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 21:51:40
Data point term sent to Coder	System	09 Mar 2021 21:50:56
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:50:03
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:17
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:53:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 19:48:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 19:48:35
Data point term sent to Coder	System	11 Nov 2020 19:47:52
User entered 'Hydrocodone/acetaminophen'	Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:06

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
DataPoint Verified.		03 Mar 2021 20:17:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:06

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:06:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:05:57
User closed query 'Please source indication is noted as Right scaphoid fracture. Please confirm with source and update accordingly.' (Site from CRA). Query 'Please source indication is noted as Right scaphoid fracture. Please confirm with source and update accordingly.' answered with 'yes, that is correct, data now corrected, thank you' (Site from CRA).	(b) (4) Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 15:05:55 09 Mar 2021 21:50:08
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:50:03
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:50:03
User entered 'RIGHT SCAPHOID fracture' reason for change: Data Entry Error	Elisa Moralez (b) (4)	09 Mar 2021 21:50:03
User opened query 'Please source indication is noted as Right scaphoid fracture. Please confirm with source and update accordingly.' (Site from CRA). Query 'Please confirm indication as there is no corresponding AE.' canceled (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:31:49 05 Mar 2021 18:30:40 03 Mar 2021 20:17:17
User opened query 'Please confirm indication as there is no corresponding AE.' (Site from CRA). User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	03 Mar 2021 20:16:43 26 Feb 2021 03:53:10
User entered 'right scaphoid pain'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:06



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
DataPoint Verified.		03 Mar 2021 20:17:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '10/325'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:06

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
DataPoint Verified.		03 Mar 2021 20:17:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'mg (mg)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:06

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
DataPoint Verified.		03 Mar 2021 20:17:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:06

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:06:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:06:54
DataPoint Un-verified.	Elisa Morales (b) (4)	17 Mar 2021 14:43:05
Signature has been broken.	(b) (4) Elisa Morales (b) (4)	17 Mar 2021 14:43:05
User entered 'four times daily (QID)' reason for change: Data Entry Error	(b) (4) Elisa Morales (b) (4)	17 Mar 2021 14:43:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Mar 2021 20:17:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'other (OTHER)'	(b) (4) Elisa Morales (b) (4)	11 Nov 2020 19:47:06
	(b) (4)	

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:06:56
User closed query 'Per CDM: Please clarify if "Q 6 hours" means that subject takes medication every 6 hours. If yes, then please consider selecting from the dropdown "Four times daily". Thank you!' ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:42:01
DataPoint Verified.		17 Mar 2021 15:06:56
DataPoint Un-verified.	Elisa Moralez (b) (4)	17 Mar 2021 14:43:05
Signature has been broken.	(b) (4) Elisa Moralez (b) (4)	17 Mar 2021 14:43:05
User entered empty; reason for change Data Entry Error	(b) (4) Elisa Moralez (b) (4)	17 Mar 2021 14:43:05
Query 'Per CDM: Please clarify if "Q 6 hours" means that subject takes medication every 6 hours. If yes, then please consider selecting from the dropdown "Four times daily". Thank you!' ' answered with 'ok' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 14:42:57
User opened query 'Per CDM: Please clarify if "Q 6 hours" means that subject takes medication every 6 hours. If yes, then please consider selecting from the dropdown "Four times daily". Thank you!' ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 11:02:34
DataPoint Verified.		03 Mar 2021 20:17:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'once every 6 hours'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:06

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
DataPoint Verified.		03 Mar 2021 20:17:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Oral (ORAL)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:06

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
DataPoint Verified.		03 Mar 2021 20:17:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:06

**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:07:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
DataPoint Verified.		03 Mar 2021 20:17:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '28 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:06



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
DataPoint Verified.		03 Mar 2021 20:17:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:06

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
DataPoint Verified.		03 Mar 2021 20:17:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:06

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
DataPoint Verified.		03 Mar 2021 20:17:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '29 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:06

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:07:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
DataPoint Verified.		03 Mar 2021 20:17:17
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:06

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:07:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
User entered '4'	System	17 Mar 2021 14:43:05
User entered empty.	System	11 Nov 2020 19:47:06

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
User entered '1'	System	17 Mar 2021 14:43:05
User entered empty.	System	11 Nov 2020 19:47:06

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:00
User entered '804 (804)'	System	17 Mar 2021 14:43:05
User entered empty.	System	11 Nov 2020 19:47:06

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 16:41:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Mar 2021 16:41:52
Data point term sent to Coder	System	09 Mar 2021 21:50:56
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:50:18
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:17:18
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:53:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:42:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:42:42
Data point term sent to Coder	System	11 Nov 2020 19:47:52
User entered 'Doxycycline'	Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
DataPoint Verified.		03 Mar 2021 20:17:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:06:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Mar 2021 15:07:09
User closed query 'Per source indication is noted as Right scaphoid fracture. Please confirm with source and update accordingly.' (Site from CRA).		17 Mar 2021 15:07:07
Query 'Per source indication is noted as Right scaphoid fracture. Please confirm with source and update accordingly.' answered with 'yes, that is correct, data now corrected, thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:50:21
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:50:18
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 21:50:18
User entered 'RIGHT SCAPHOID fracture' reason for change: Data Entry Error	Elisa Moralez (b) (4)	09 Mar 2021 21:50:18
User opened query 'Per source indication is noted as Right scaphoid fracture. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 18:32:43
Query 'Please confirm indication as there is no corresponding AE.' canceled (Site from CRA).		03 Mar 2021 20:24:45
DataPoint Verified.		03 Mar 2021 20:17:18
User opened query 'Please confirm indication as there is no corresponding AE.' (Site from CRA).		03 Mar 2021 20:16:01
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 03:53:10
User entered 'right scaphoid surgery'	Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
DataPoint Verified.		03 Mar 2021 20:17:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '100'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
DataPoint Verified.		03 Mar 2021 20:17:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'mg (mg)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
DataPoint Verified.		03 Mar 2021 20:17:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
DataPoint Verified.		03 Mar 2021 20:17:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'twice daily (BID)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
DataPoint Verified.		03 Mar 2021 20:17:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34

**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:07:47**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
DataPoint Verified.		03 Mar 2021 20:17:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Oral (ORAL)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
DataPoint Verified.		03 Mar 2021 20:17:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
DataPoint Verified.		03 Mar 2021 20:17:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '28 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
DataPoint Verified.		03 Mar 2021 20:17:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
DataPoint Verified.		03 Mar 2021 20:17:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
DataPoint Verified.		03 Mar 2021 20:17:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '30 Oct 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
DataPoint Verified.		03 Mar 2021 20:17:18
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	11 Nov 2020 19:47:34

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:07:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
User entered '2'	System	11 Nov 2020 19:47:34

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
User entered '1'	System	11 Nov 2020 19:47:34



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:07:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:04
User entered '804 (804)'	System	11 Nov 2020 19:47:34

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
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.	(b) (4) Coder Import (b) (4) (b) (4)	25 Nov 2020 17:33:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 17:33:10
Data point term sent to Coder	System	25 Nov 2020 17:32:10
User entered 'Influenza vaccine'	(b) (4), (b) (6)	25 Nov 2020 17:31:44

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:31:44

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Influenza Prophylaxis'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:31:44

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'l'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:31:44

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:31:44

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User closed query 'Per CDM: Please consider removing '1' from dose unit '1 Injection" (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 18:52:05
Query 'Per CDM: Please consider removing '1' from dose unit '1 Injection" answered with 'Updated' (Site from DM).		03 Dec 2020 22:08:16
User entered 'INJECTION' reason for change: Data Entry Error		03 Dec 2020 22:08:07
User opened query 'Per CDM: Please consider removing '1' from dose unit '1 Injection" (Site from DM).		03 Dec 2020 06:28:59
User entered '1 Injection'		25 Nov 2020 17:31:44

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	(b) (4)	
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	25 Nov 2020 17:31:59
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	25 Nov 2020 17:31:59
User entered 'once (ONCE)'	System	25 Nov 2020 17:31:44
	(b) (4), (b) (6)	25 Nov 2020 17:31:44



US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:31:44

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:31:44

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:31:44

**US3322302**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:07:47**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '3 Nov 2020'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:31:44

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '0'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:31:44

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:31:44

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4) System	25 Nov 2020 17:31:59
User entered '3 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 17:31:59
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	25 Nov 2020 17:31:44
User entered '2 Nov 2020'	(b) (4), (b) (6)	25 Nov 2020 17:31:44

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
DataPoint Verified.		03 Mar 2021 20:18:03
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Nov 2020 17:31:44



US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:07:47**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
User entered empty.	System	25 Nov 2020 17:31:44

US3322302

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:07:47**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
User entered empty.	System	25 Nov 2020 17:31:44

US3322302

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:07:47

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:42:07
User entered empty.	System	25 Nov 2020 17:31:44

US3322302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:07:47

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:29
DataPoint Verified.		03 Mar 2021 20:18:13
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Nov 2020 14:30:54

US3322302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:07:47

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:18:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered '28 Oct 2020'	Elisa Moralez (b) (4)	12 Nov 2020 14:31:14

US3322302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:07:47

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:18:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User closed query 'Per ETRTR: Please confirm Surgery did not require patient Hospitalization. Otherwise update AE folder with surgery information, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:41:41
Query 'Per ETRTR: Please confirm Surgery did not require patient Hospitalization. Otherwise update AE folder with surgery information, thanks.' answered with 'per source, surgery did not require patient hospitalization' (Site from CRA).	Frances Saubon (b) (4) (b) (4)	01 Dec 2020 20:11:13
User opened query 'Per ETRTR: Please confirm Surgery did not require patient Hospitalization. Otherwise update AE folder with surgery information, thanks.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 16:58:44
User entered 'Right Scaphoid Surgery'	Elisa Moralez (b) (4) (b) (4)	12 Nov 2020 14:31:14

US3322302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:07:47

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:18:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 16:42:40
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' answered with 'will update AE form immediately, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	02 Dec 2020 14:19:53
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 09:49:51
User entered 'Adverse Event (AE)'	Elisa Moralez (b) (4) (b) (4)	12 Nov 2020 14:31:14

US3322302

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:07:47

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:18:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:10
User entered empty.	Elisa Moralez (b) (4)	12 Nov 2020 14:31:14



US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'USA-US060-2020-MRNA-1273-P301000009'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Yes (Y)'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Yes (Y)'	System	12 Nov 2020 16:23:40



US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
System		28 Dec 2020 14:43:34
User entered 'Teresa'	System	28 Dec 2020 14:43:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Veronica'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
System		28 Dec 2020 14:43:34
User entered 'Becker'	System	28 Dec 2020 14:43:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Fragoso'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered '6550 Mapleridge Street'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Houston'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	28 Dec 2020 14:43:34
Reviewed for Safety.	System	28 Dec 2020 14:43:34
	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'TX'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered '77081'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:15:47
User entered 'US'	System	12 Nov 2020 16:24:03

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
	(b) (4)	
User entered '4'	System	28 Dec 2020 14:43:34
User entered '3'	System	03 Dec 2020 17:13:57
User entered '2'	System	02 Dec 2020 15:16:04
User entered '1'	System	12 Nov 2020 16:24:03



US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'USA-US060-2020-MRNA-1273-P301000009'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Yes (Y)'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Yes (Y)'	System	12 Nov 2020 16:23:40



US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
User entered 'Teresa'	System	28 Dec 2020 14:43:34
Reviewed for Safety.	System	28 Dec 2020 14:43:34
	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Veronica'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
User entered 'Becker'	System	28 Dec 2020 14:43:34
Reviewed for Safety.	System	28 Dec 2020 14:43:34
	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Fragoso'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered '6550 Mapleridge Street'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Houston'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
System		28 Dec 2020 14:43:34
User entered empty.	System	28 Dec 2020 14:43:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'TX'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered '77081'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:15:47
User entered 'US'	System	12 Nov 2020 16:24:03

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
	(b) (4)	
User entered '4'	System	28 Dec 2020 14:43:34
User entered '3'	System	03 Dec 2020 17:13:57
User entered '2'	System	02 Dec 2020 15:16:04
User entered '1'	System	12 Nov 2020 16:24:03



**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:07:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '12/Nov/2020 11:24'	(b) (4) System	12 Nov 2020 16:24:03

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:07:47

**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)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:15:47
User entered 'I'		12 Nov 2020 16:24:03

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'USA-US060-2020-MRNA-1273-P301000009'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Yes (Y)'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40



**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Yes (Y)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
System		28 Dec 2020 14:43:34
User entered 'Teresa'	System	28 Dec 2020 14:43:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Veronica'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
System		28 Dec 2020 14:43:34
User entered 'Becker'	System	28 Dec 2020 14:43:34
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Fragoso'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered '6550 Mapleridge Street'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Houston'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	28 Dec 2020 14:43:34
Reviewed for Safety.	System	28 Dec 2020 14:43:34
	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'TX'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered '77081'	System	12 Nov 2020 16:23:40



US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:15:47
User entered 'US'	System	12 Nov 2020 16:24:03

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
	(b) (4)	
User entered '4'	System	28 Dec 2020 14:43:34
User entered '3'	System	03 Dec 2020 17:13:57
User entered '2'	System	02 Dec 2020 15:16:04
User entered '1'	System	12 Nov 2020 16:24:03

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:07:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '02/Dec/2020 15:16'	(b) (4) System	02 Dec 2020 15:16:04

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:07:47

**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)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 17:13:46
User entered 'I'		02 Dec 2020 15:16:04

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'USA-US060-2020-MRNA-1273-P301000009'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Yes (Y)'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40



**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Yes (Y)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
User entered 'Teresa'	System	28 Dec 2020 14:43:34
Reviewed for Safety.	System	28 Dec 2020 14:43:34
	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Veronica'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
User entered 'Becker'	System	28 Dec 2020 14:43:34
Reviewed for Safety.	System	28 Dec 2020 14:43:34
	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Fragoso'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered '6550 Mapleridge Street'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Houston'	System	12 Nov 2020 16:23:40



US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	28 Dec 2020 14:43:34
Reviewed for Safety.	System	28 Dec 2020 14:43:34
	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'TX'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered '77081'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:15:47
User entered 'US'	System	12 Nov 2020 16:24:03

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
	(b) (4)	
User entered '4'	System	28 Dec 2020 14:43:34
User entered '3'	System	03 Dec 2020 17:13:57
User entered '2'	System	02 Dec 2020 15:16:04
User entered '1'	System	12 Nov 2020 16:24:03

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:07:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '03/Dec/2020 12:13'	(b) (4) System	03 Dec 2020 17:13:57

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:07:47

**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)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Dec 2020 22:05:19
User entered 'I'		03 Dec 2020 17:13:57

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'USA-US060-2020-MRNA-1273-P301000009'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Yes (Y)'	System	12 Nov 2020 16:23:40



**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'No (N)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Yes (Y)'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
User entered 'Teresa'	System	28 Dec 2020 14:43:34
Reviewed for Safety.	System	28 Dec 2020 14:43:34
	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Veronica'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
User entered 'Becker'	System	28 Dec 2020 14:43:34
Reviewed for Safety.	System	28 Dec 2020 14:43:34
	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Fragoso'	System	12 Nov 2020 16:23:40



**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered '6550 Mapleridge Street'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'Houston'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	28 Dec 2020 14:43:34
Reviewed for Safety.	System	28 Dec 2020 14:43:34
	(b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered 'TX'	System	12 Nov 2020 16:23:40

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:07:47**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:23:55
User entered '77081'	System	12 Nov 2020 16:23:40

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 15:15:47
User entered 'US'	System	12 Nov 2020 16:24:03

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:07:47

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
	(b) (4)	
User entered '4'	System	28 Dec 2020 14:43:34
User entered '3'	System	03 Dec 2020 17:13:57
User entered '2'	System	02 Dec 2020 15:16:04
User entered '1'	System	12 Nov 2020 16:24:03

**US3322302**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000009**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:07:47**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered '28/Dec/2020 09:43'	(b) (4) System	28 Dec 2020 14:43:34

US3322302

Folder: SAE USA-US060-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:07:47

**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)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 20:21:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 03:53:14
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:43:34