

US3322409 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:19:05

All time stamps listed in this document are displayed in GMT

US3322409

Form: Participant Creation

Data signed: (b) (4) 26 Feb 2021 04:12:59

Generated On: 11 Aug 2021 22:19:05

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[Participant ID](#)

US3322409

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

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US3322409

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Date of Birth (MMM yyyy)	(b) (6) 1989
Age	31
Age Units	YEARS
Age (Derived)	31
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	True
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 04:13:02

Generated On: 11 Aug 2021 22:19:05

Date of Informed Consent ( <i>dd MMM yyyy</i> )	2 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" 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 04:13:02

Generated On: 11 Aug 2021 22:19:05

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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 04:13:02

Generated On: 11 Aug 2021 22:19:05

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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) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

Condition	ASPIRIN ALLERGY (HIVES GENERALIZED)
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 (2)

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

Condition	SEAFOOD ALLERGY (ITCHING)
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

Condition	HEADACHES
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)	_____

US3322409

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

Condition	EXERCISE INDUCED MUSCLE ACHES
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) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	2 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	13:10 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 13:10
Height ( <i>xxx.x</i> )	62 in
Weight ( <i>xxx.x</i> )	115 lb
BMI ( <i>xxx.x</i> )	21.07775 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 OCT 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 26 Feb 2021 04:13:02

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Date of assessment (dd MMM yyyy) 2 OCT 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	2 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 04:13:02

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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**

RESEARCH COORDINATOR,  
WILL BE BACK TO WORK FROM  
NEXT WEEK

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

**No Risk Identified** False

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

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PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 04:13:02

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	True
<b>Specify</b>	LIVES WITH BOYFRIEND AND HER PARENTS IN THE HOUSE. BOYFRIEND IS NURSE AT HIGH RISK. FATHER WORKS AT RESTAURANT. MOTHER IS SALES PERSON AT (b) (6). PT GOES TO GYM WITH FRIENDS 2X PER WEEK

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:13:03

Generated On: 11 Aug 2021 22:19:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Feb 2021 04:13:03

Generated On: 11 Aug 2021 22:19:05

What was the date of randomization? (dd MMM yyyy) 02 OCT 2020

What was the participant's randomization number? 116334

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 04:13:03

Generated On: 11 Aug 2021 22:19:05

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 04:13:03

Generated On: 11 Aug 2021 22:19:05

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)	2 OCT 2020
Time of assessment (00:00-23:59)	13:19 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 13:19
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 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 04:13:03

Generated On: 11 Aug 2021 22:19:05

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 OCT 2020
Time of assessment (00:00-23:59)	15:24 (24 HR)
Vital Signs Date and Time (derived)	2 OCT 2020 15:24
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 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 04:13:03

Generated On: 11 Aug 2021 22:19:05

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: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 04:13:03

Generated On: 11 Aug 2021 22:19:05

Was the pregnancy test performed? Yes ☐  
No ☒

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

Test performed Urine ☐  
Serum ☐

Result Positive ☐  
Negative ☐

Was FSH sample collected? Yes ☐  
No ☐

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

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

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

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) 2 OCT 2020

What was the treatment time? (00:00-23:59) 14:25 (24 HR)

Treatment Date and Time (derived) 2 OCT 2020 14:25

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 04:13:02

Generated On: 11 Aug 2021 22:19:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 OCT 2020
Collection time (00:00-23:59)	14:25 (24 HR)
Collection date and time (derived)	2 OCT 2020 14:25

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Collection date (dd MMM yyyy)			2 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:20	2 OCT 2020 14:20
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 15:24

PC Open Date & Time

02 OCT 2020 15:08

PC Close Date & Time

02 OCT 2020 17:38

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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 02 OCT 2020 21:09

PC Open Date & Time 02 OCT 2020 18:10

PC Close Date & Time 03 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 12:01

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	04 OCT 2020 13:34
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

05 OCT 2020 12:05

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 12:00

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**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

98.9 °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

07 OCT 2020 16:08

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 12:01

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**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

02 OCT 2020 15:25

PC Open Date & Time

02 OCT 2020 15:08

PC Close Date & Time

02 OCT 2020 17:38

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**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

02 OCT 2020 21:09

PC Open Date & Time

02 OCT 2020 18:10

PC Close Date & Time

03 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**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

03 OCT 2020 12:02

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59



US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**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

04 OCT 2020 13:34

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 4
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	05 OCT 2020 12:05
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**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

06 OCT 2020 12:01

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**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

07 OCT 2020 16:08

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 7
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	08 OCT 2020 12:02
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**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 ☐

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 15:25
PC Open Date & Time	02 OCT 2020 15:08
PC Close Date & Time	02 OCT 2020 17:38

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**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 ☐



US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 21:10
PC Open Date & Time	02 OCT 2020 18:10
PC Close Date & Time	03 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 12:02
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**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

51 of 3098

EAB) (1725)

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 13:35
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

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

53 of 3098

EAB) (1725)

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 12:06
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:19:05

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 ☒



US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:19:05

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 12:01
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

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 ☒

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 16:08
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

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 ☒

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EAB) (1725)

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 12:02
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3322409

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322409

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322409

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3322409

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322409

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322409

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322409

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:13:03

Generated On: 11 Aug 2021 22:19:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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	VISIT2

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 04:13:03

Generated On: 11 Aug 2021 22:19:05

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)	5 NOV 2020
Time of assessment (00:00-23:59)	15:30 (24 HR)
Vital Signs Date and Time (derived)	5 NOV 2020 15:30
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 04:13:03

Generated On: 11 Aug 2021 22:19:05

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)	5 NOV 2020
Time of assessment (00:00-23:59)	17:18 (24 HR)
Vital Signs Date and Time (derived)	5 NOV 2020 17:18
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3322409

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:13:03

Generated On: 11 Aug 2021 22:19:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 NOV 2020

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

US3322409

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 04:13:03

Generated On: 11 Aug 2021 22:19:05

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 05 NOV 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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



US3322409

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 04:13:03

Generated On: 11 Aug 2021 22:19:05

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) 05 NOV 2020

What was the treatment time? (00:00-23:59) 16:48 (24 HR)

Treatment Date and Time (derived) 05 NOV 2020 16:48

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

US3322409

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 04:13:03

Generated On: 11 Aug 2021 22:19:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 NOV 2020
Collection time (00:00-23:59)	16:30 (24 HR)
Collection date and time (derived)	5 NOV 2020 16:30

US3322409

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 04:13:03

Generated On: 11 Aug 2021 22:19:05

Collection date (dd MMM yyyy)			5 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:25	5 NOV 2020 16:25
Nasopharyngeal Swab 2	No		

US3322409

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:13:03

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 NOV 2020 17:19

PC Open Date & Time

05 NOV 2020 17:08

PC Close Date & Time

05 NOV 2020 19:38

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**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 98.9 °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	05 NOV 2020 22:57
PC Open Date & Time	05 NOV 2020 20:33
PC Close Date & Time	06 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 NOV 2020 12:00

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

07 NOV 2020 13:10

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59



US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**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

98.9 °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

08 NOV 2020 13:42

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 NOV 2020 12:01

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 6

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

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

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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

99.3 °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 NOV 2020 12:08

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 NOV 2020 12:01

PC Open Date & Time

11 NOV 2020 12:00

PC Close Date & Time

12 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 NOV 2020 17:20

PC Open Date & Time

05 NOV 2020 17:08

PC Close Date & Time

05 NOV 2020 19:38

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**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

05 NOV 2020 22:57

PC Open Date & Time

05 NOV 2020 20:33

PC Close Date & Time

06 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**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

06 NOV 2020 12:01

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**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

07 NOV 2020 13:11

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59



US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**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

08 NOV 2020 13:42

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**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

09 NOV 2020 12:02

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**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

10 NOV 2020 12:08

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 7
Please record - <b>PAIN AT INJECTION SITE.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
Is there any <b>REDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Is there any <b>SWELLING/HARDNESS AT INJECTION SITE?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Please record - <b>UNDERARM GLAND SWELLING OR TENDERNESS.</b>	None <input checked="" type="radio"/>
Please select one response below	
Does not interfere with activity	<input type="radio"/>
Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity	<input type="radio"/>
Any use of prescription pain reliever or prevents daily activity	<input type="radio"/>
PC Time Stamp	11 NOV 2020 12:01
PC Open Date & Time	11 NOV 2020 12:00
PC Close Date & Time	12 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**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 ☐

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

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

No ☒

Yes ☐

PC Time stamp	05 NOV 2020 17:20
PC Open Date & Time	05 NOV 2020 17:08
PC Close Date & Time	05 NOV 2020 19:38

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**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 ☐

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

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

No ☒

Yes ☐

PC Time stamp	05 NOV 2020 22:58
PC Open Date & Time	05 NOV 2020 20:33
PC Close Date & Time	06 NOV 2020 11:59



US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**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 ☒

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

Yes <input type="checkbox"/>	
PC Time stamp	06 NOV 2020 12:01
PC Open Date & Time	06 NOV 2020 12:00
PC Close Date & Time	07 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

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 ☒

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

Yes <input type="checkbox"/>	
PC Time stamp	07 NOV 2020 13:11
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

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 ☒

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

Yes <input type="checkbox"/>	
PC Time stamp	08 NOV 2020 13:43
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:19:05

Yes <input type="checkbox"/>	
PC Time stamp	09 NOV 2020 12:02
PC Open Date & Time	09 NOV 2020 12:00
PC Close Date & Time	10 NOV 2020 11:59



US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

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 ☒

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

Yes <input type="checkbox"/>	
PC Time stamp	10 NOV 2020 12:08
PC Open Date & Time	10 NOV 2020 12:00
PC Close Date & Time	11 NOV 2020 11:59

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 7

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

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

US3322409

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322409

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322409

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322409

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3322409

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322409

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322409

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:13:03

Generated On: 11 Aug 2021 22:19:05

Was this visit performed? Yes ☐  
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐  
Clinic ☐

Folder OID VISIT3

US3322409

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:13:03

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	30 NOV 2020 14:39:05
Patient Cloud Open Date & Time	29 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	116 of 3098

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 00:03:35
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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	13 DEC 2020 01:43:46
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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 <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 DEC 2020 15:33:55
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 09:11:43
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 00:52:46
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 00:01:28
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 00:08:00
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 00:02:18
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 FEB 2021 07:03:56
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 00:21:57
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

<b>TIMEPOINT</b>	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 00:01:37
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	21 FEB 2021 00:01:41
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 FEB 2021 06:51:14
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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

07 MAR 2021 00:25:11

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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

15 MAR 2021 11:27:22

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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

21 MAR 2021 00:08:40

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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

28 MAR 2021 00:02:18

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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

04 APR 2021 00:02:15

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 00:39:19

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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

19 APR 2021 10:48:01

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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

25 APR 2021 08:40:07

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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

02 MAY 2021 00:16:28

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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 <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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 250

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

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 271

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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 <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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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 <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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Close Date & Time](#)

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23 DEC 2021 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Open Date & Time](#)

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06 FEB 2022 00:01

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10 FEB 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

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20 FEB 2022 00:01

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24 FEB 2022 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

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27 FEB 2022 00:01

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03 MAR 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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06 MAR 2022 00:01

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10 MAR 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

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13 MAR 2022 00:01

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17 MAR 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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°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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 544

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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27 MAR 2022 00:01

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31 MAR 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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°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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

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03 APR 2022 00:01

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07 APR 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Open Date & Time](#)

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10 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

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17 APR 2022 00:01

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21 APR 2022 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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24 APR 2022 00:01

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28 APR 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

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01 MAY 2022 00:01

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05 MAY 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 621

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

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

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

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

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

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

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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°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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Open Date & Time](#)

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10 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUL 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

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21 JUL 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

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28 JUL 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Open Date & Time](#)

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14 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 691

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

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

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

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

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

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

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Open Date & Time](#)

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02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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°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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Close Date & Time](#)

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10 NOV 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

**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 ☐

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Open Date & Time](#)

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20 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 NOV 2022 23:59

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US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59



US3322409

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:19:05

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"/>

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

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[Patient Cloud Open Date & Time](#)

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04 DEC 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 DEC 2022 23:59

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US3322409

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:19:05

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		27 FEB 2021 23:47:22

US3322409

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322409

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322409

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322409

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322409

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 16:39:17

Generated On: 11 Aug 2021 22:19:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3322409

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322409

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 16:39:17

Generated On: 11 Aug 2021 22:19:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322409

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 16:39:17

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322409

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 16:39:20

Generated On: 11 Aug 2021 22:19:05

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

Visit date (dd MMM yyyy)	19 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3322409

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 16:39:20

Generated On: 11 Aug 2021 22:19:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 APR 2021
Time of assessment (00:00-23:59)	11:46 (24 HR)
Vital Signs Date and Time (derived)	19 APR 2021 11:46
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	107 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322409

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 16:39:20

Generated On: 11 Aug 2021 22:19:05

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.*

US3322409

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 16:39:20

Generated On: 11 Aug 2021 22:19:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 APR 2021

Collection time (00:00-23:59)

12:03 (24 HR)

Collection date and time (derived)

19 APR 2021 12:03

US3322409

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 16:39:17

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3322409**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

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*

**US3322409**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Date of Contact	13 NOV 2020
Time of Contact	8:57
Date and Time of Contact (derived)	13 NOV 2020 8:57
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	7 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	8 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	9 NOV 2020
------	------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.7 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Feb 2021 04:13:00

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (12)

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (12)

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (13)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input checked="" type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (13)

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 26 Feb 2021 04:13:00

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input checked="" type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (14)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	20 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.1 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Data signed: (b) (4) 26 Feb 2021 04:13:00

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (15)

Data signed: (b) (4) 26 Feb 2021 04:13:00

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input checked="" type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	21 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	97.6 F
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (15)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (16)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input checked="" type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (16)

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (16)

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Feb 2021 04:13:00

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Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Feb 2021 04:13:00

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input checked="" type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (17)

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Form: Symptom Log (18)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (18)

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Generated On: 11 Aug 2021 22:19:05

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Form: Symptom Log (19)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (19)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	25 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

O2 Saturation Units	%
---------------------	---

Temperature	99.1 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Generated On: 11 Aug 2021 22:19:05

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	26 NOV 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	97 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	98.9 F
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Nasal Congestion

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Nausea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Vomiting

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Diarrhea

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

Sore Throat

None ☒  
Mild ☐  
Moderate ☐  
Severe ☐  
Not Done ☐

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Date of Visit	13 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	13 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Did the subject have Respiratory Rates  $\geq 30$  per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Respiratory Rate \_\_\_\_\_

Did the subject have Heart Rate  $\geq 125$  beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Heart Rate \_\_\_\_\_

Did the subject have Oxygen Saturation of SpO<sub>2</sub>  $\leq 93\%$  on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

Oxygen Saturation \_\_\_\_\_

Did the subject have PaO<sub>2</sub>/FIO<sub>2</sub> Ratio  $< 300$  mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date \_\_\_\_\_

End Date \_\_\_\_\_

PaO<sub>2</sub> \_\_\_\_\_

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date \_\_\_\_\_

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date \_\_\_\_\_

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

If Yes to either Did subject require any of the following:

**Ventilator Support:**

High-Flow Oxygen? Yes ☐  
No ☐

Start Date

End Date

Non-Invasive Ventilation? Yes ☐  
No ☐

Start Date

End Date

Mechanical Ventilation? Yes ☐  
No ☐

Start Date

End Date

ECMO? Yes ☐  
No ☐

Start Date

End Date

**Evidence of Shock:**

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐  
No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐  
No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐  
No ☒

Start Date

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Hepatic Dysfunction? Yes ☐ No ☒

Start Date

Neurologic Dysfunction? Yes ☐ No ☒

Start Date

**Evidence of Pneumonia:**

Clinical Evidence Yes ☐ No ☒

Date of Assessment

Radiographical Evidence Yes ☐ No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐ No ☒

Start Date

End Date

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---



US3322409

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	16 NOV 2020
Day 5	Yes	17 NOV 2020
Day 7	Yes	19 NOV 2020
Day 9	Yes	20 NOV 2020
Day 14	Yes	25 NOV 2020
Day 21	Yes	04 DEC 2020
Day 28	Yes	09 DEC 2020

US3322409

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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	SICKD1

US3322409

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 NOV 2020
Time of assessment (00:00-23:59)	15:20 (24 HR)
Vital Signs Date and Time (derived)	13 NOV 2020 15:20
Height (xxx.x)	62 in
Weight (xxx.x)	118 lb
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322409

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 NOV 2020

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

US3322409

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

13 NOV 2020

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 DEC 2020
Time of assessment (00:00-23:59)	14:34 (24 HR)
Vital Signs Date and Time (derived)	09 DEC 2020 14:34
Height (xxx.x)	62 in
Weight (xxx.x)	116 lb
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 DEC 2020

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



US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

Was Blood Sample Taken for Immunologic Assessment of  
SARS\_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

09 DEC 2020

US3322409

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

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

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

Visit date (dd MMM yyyy)	18 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3322409

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

Form: Unblinding

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

Date of updated informed consent ( <i>dd MMM yyyy</i> )	18 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	18 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3322409

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

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

US3322409

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 JAN 2021
Time of assessment (00:00-23:59)	10:42 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 10:42
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3322409

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
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)	18 JAN 2021
Time of assessment (00:00-23:59)	14:43 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 14:43
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3322409

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

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 JAN 2021

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

US3322409

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

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Was the pregnancy test performed? Yes ☒ No ☐

Date of test (dd MMM yyyy) 18 JAN 2021

Test performed Urine ☒ Serum ☐

Result Positive ☐ Negative ☒

Was FSH sample collected? Yes ☐ No ☒

Collection date

Collection time

Collection date and time (derived)



US3322409

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

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 18 JAN 2021

What was the treatment time? (00:00-23:59) 14:06 (24 HR)

Treatment Date and Time (derived) 18 JAN 2021 14:06

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

US3322409

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

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

Collection date (dd MMM yyyy)	18 JAN 2021
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Collection time (00:00-23:59)	13:39 (24 HR)
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Collection date and time (derived)	18 JAN 2021 13:39
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US3322409

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

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

Collection date (dd MMM yyyy)	18 JAN 2021
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Collection time (00:00 - 23:59)	13:34
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Collection Date and Time (derived)	18 JAN 2021 13:34
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US3322409

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

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322409

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322409

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:13:02

Generated On: 11 Aug 2021 22:19:05

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

US3322409

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

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)	12 FEB 2021
Time of assessment (00:00-23:59)	11:26 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 11:26
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG



US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

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)	12 FEB 2021
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 13:10
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3322409

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 FEB 2021

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

US3322409

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	12 FEB 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3322409

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 12 FEB 2021

What was the treatment time? (00:00-23:59) 12:33 (24 HR)

Treatment Date and Time (derived) 12 FEB 2021 12:33

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

US3322409

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:13:01

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322409

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3322409

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322409

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57



US3322409

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

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) \_\_\_\_\_

US3322409

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

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.*

US3322409

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

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

Collection date (dd MMM yyyy)	12 MAR 2021
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Collection time (00:00-23:59)	12:49 (24 HR)
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Collection date and time (derived)	12 MAR 2021 12:49
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US3322409

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 24 Mar 2021 22:12:51

Generated On: 11 Aug 2021 22:19:05

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 00:02:09

Generated On: 11 Aug 2021 22:19:05

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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 01 Apr 2021 00:02:09

Generated On: 11 Aug 2021 22:19:05

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 Apr 2021 00:02:09

Generated On: 11 Aug 2021 22:19:05

AEID

Adverse event

DOG BITE (LEFT/RIGHT THIGH)

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

23 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 01 Apr 2021 00:02:09

Generated On: 11 Aug 2021 22:19:05

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



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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 01 Apr 2021 00:02:09

Generated On: 11 Aug 2021 22:19:05

AEID	USA-US060-2020-MRNA-1273-P30 1000011
Adverse event	SYMPTOMATIC COVID-19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	07 NOV 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)	04 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 01 Apr 2021 00:02:09

Generated On: 11 Aug 2021 22:19:05

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

US3322409

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 01 Apr 2021 00:02:09

Generated On: 11 Aug 2021 22:19:05

AEID

Adverse event

TENNIS ELBOW

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

09 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 01 Apr 2021 00:02:09

Generated On: 11 Aug 2021 22:19:05

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

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

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

Yes ☒

No ☐

---

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

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US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

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 (1)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

Name of Medication NAPROXEN

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE ACHES

Dose per administration 220

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) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

	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)		4 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) 4 OCT 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

Name of Medication NORTRIPTYLINE

Prophylaxis Yes ☐  
No ☒

Indication SHINGLES

Dose per administration 25

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) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	19 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input 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) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

Name of Medication VALCYCLOVIR

Prophylaxis Yes ☐  
No ☒

Indication SHINGLES

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

1 GM NOW & 1 TAB PO DAILY X  
7 DAYS

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

	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)	19 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)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

Name of Medication ACYCLOVIR (5%)

Prophylaxis Yes ☐  
No ☒

Indication SHINGLES

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 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 (6)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication DOG BITE

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

	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)		23 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)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 19:34:11

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Name of Medication AMOXICILLIN/CLAVULANATE  
POTASSIUM

Prophylaxis Yes ☐  
No ☒

Indication DOG BITE

Dose per administration 875 /125

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

	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)	23 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)	02 NOV 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 (8)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

Name of Medication KETOROLAC

Prophylaxis Yes ☐  
No ☒

Indication DOG BITE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

	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)		23 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)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

Name of Medication BACTROBAN (2%)

Prophylaxis Yes ☐  
No ☒

Indication DOG BITE

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

	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)	23 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)	01 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
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 (10)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

Name of Medication GUAIFENESIN

Prophylaxis Yes ☐  
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

	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)	07 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHES

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

Name of Medication PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication TENNIS ELBOW

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 (12)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

	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)		09 JAN 2021
Start date completely unknown		False
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 15 JAN 2021		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	803 <input type="checkbox"/>
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Apr 2021 19:34:11

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Name of Medication PRENATAL MULTIVITAMINS

Prophylaxis Yes ☒  
No ☐

Indication PREGNANCY

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 (13)

Data signed: (b) (4) 15 Apr 2021 19:34:11

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 FEB 2021	
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 (14)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

Name of Medication SIMETHICONE (GAS-X)

Prophylaxis Yes ☐  
No ☒

Indication PREGNANCY

Dose per administration 2

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 (14)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

	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 MAR 2021	
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 (15)

Data signed: (b) (4) 15 Apr 2021 19:34:11

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Name of Medication ONDANSETRON (ZOFTRAN)

Prophylaxis Yes ☐  
No ☒

Indication NAUSEA/VOMITING

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

	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)	14 MAR 2021	
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 (16)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL CRAMPS  
(PREGNANCY)

Dose per administration 500

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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Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Apr 2021 19:34:11

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	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)		18 FEB 2021
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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Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Apr 2021 19:34:11

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Name of Medication TETANUS, DIPHTHERIA,  
PERTUSSIS VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PREVENTATIVE HEALTHCARE

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Apr 2021 19:34:11

Generated On: 11 Aug 2021 22:19:05

	Intraocular	<input type="radio"/>
	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)	23 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3322409

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Feb 2021 04:13:00

Generated On: 11 Aug 2021 22:19:05

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---



US3322409

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:19:05

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

US3322409

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:19:05

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 ☐

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

SAEID	USA-US060-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

SAEID	USA-US060-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	17/NOV/2020 14:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

SAEID	USA-US060-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	30/NOV/2020 18:27
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

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

SAEID	USA-US060-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	21/DEC/2020 15:13
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

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

SAEID	USA-US060-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	22/DEC/2020 17:38
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

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

SAEID	USA-US060-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	30/DEC/2020 17:21
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



US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

SAEID	USA-US060-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/JAN/2021 09:38
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

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form (7)

Data signed: (b) (4) 24 Mar 2021 22:12:52

Generated On: 11 Aug 2021 22:19:05

SAEID	USA-US060-2020-MRNA-1273-P301000011
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	19/MAR/2021 15:32
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

US3322409 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

**US3322409**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:19:05**

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:43:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'US3322409'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	02 Oct 2020 18:12:47

**US3322409**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:55:51
User entered 'Yes (Y)'		02 Oct 2020 21:18:42

US3322409

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:55:51
User entered '02 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Oct 2020 18:12:48

US3322409

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:55:51
User entered 'Clinic (Clinic)'		02 Oct 2020 21:18:42

**US3322409**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered 'SCRN'	System	02 Oct 2020 21:18:42



US3322409

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:19:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:19
User entered (b) (6) 1989'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Oct 2020 18:12:50

**US3322409**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:19:05**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:19
User entered '31'		02 Oct 2020 21:19:16

**US3322409**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:19:05**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered 'YEARS'	System	02 Oct 2020 21:19:16

**US3322409**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:19:05**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered '31'	System	02 Oct 2020 19:51:43

**US3322409**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:19:05**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:19
User entered 'Female (F)'		02 Oct 2020 21:19:16

US3322409

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:19:05

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'		02 Oct 2020 21:19:16

**US3322409**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:19:05**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:19
User entered '0'		02 Oct 2020 21:19:16

**US3322409**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:19:05**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:19
User entered '0'		02 Oct 2020 21:19:16



**US3322409**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:19:05**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:19
User entered 'I'		02 Oct 2020 21:19:16

**US3322409**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:19:05**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:19
User entered '0'		02 Oct 2020 21:19:16

**US3322409**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:19:05**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:19
User entered '0'		02 Oct 2020 21:19:16

US3322409

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:19:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 20:56:19
User entered '0'		02 Oct 2020 21:19:16

US3322409

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:19:05

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:19
User entered empty.		02 Oct 2020 21:19:16

**US3322409**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:19:05**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:19
User entered '0'		02 Oct 2020 21:19:16

**US3322409**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:19:05**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:19
User entered '0'		02 Oct 2020 21:19:16

US3322409

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:19:05

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:56:41
User entered '2 Oct 2020'	Frances Saubon (b) (4)	02 Oct 2020 19:51:43



US3322409

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered 'Oct 2020'	System	02 Oct 2020 19:51:43

**US3322409**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered '2020'	System	02 Oct 2020 19:51:43

US3322409

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:19:05

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:41
User entered 'Amendment 4 (4)'	Frances Saubon (b) (4) (b) (4)	02 Oct 2020 19:51:43

US3322409

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:41
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	02 Oct 2020 19:51:43

**US3322409**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:19:05**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:41
User entered empty.	Frances Saubon (b) (4) (b) (4)	02 Oct 2020 19:51:43

US3322409

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:19:05

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:41
User entered empty.	Frances Saubon (b) (4) (b) (4)	02 Oct 2020 19:51:43

US3322409

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:19:05

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:56:41
User entered 'No (N)'	Frances Saubon (b) (4)	02 Oct 2020 19:51:43

US3322409

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:19:05

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:56:41
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	02 Oct 2020 18:12:48



US3322409

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:19:05

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered 'I'	System	02 Oct 2020 19:51:48

US3322409

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:05
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	02 Oct 2020 19:51:48

US3322409

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:19:05

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:13
User entered 'Yes (Y)'		02 Oct 2020 21:19:30

US3322409

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:19:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria drug-induced - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:21:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 07:21:43
Data point term sent to Coder	System	02 Oct 2020 21:20:55
User entered 'Aspirin allergy (hives generalized)'	(b) (4), (b) (6)	02 Oct 2020 21:19:57

**US3322409**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered 'UN UNK 2016'		02 Oct 2020 21:19:57

**US3322409**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered '0'		02 Oct 2020 21:19:57

**US3322409**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered 'Yes (Y)'		02 Oct 2020 21:19:57

US3322409

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Signature has been broken.	(b) (4) Elisa Moralez (b) (4)	05 Mar 2021 22:11:12
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered empty.		02 Oct 2020 21:19:57



**US3322409**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered '0'		02 Oct 2020 21:19:57

US3322409

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:19:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered 'Jan 2016'	System	02 Oct 2020 21:19:57

**US3322409**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered '2016'	System	02 Oct 2020 21:19:57

**US3322409**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered empty.	System	02 Oct 2020 21:19:57

**US3322409**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered empty.	System	02 Oct 2020 21:19:57

US3322409

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:19:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Seafood allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 05:06:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 05:06:52
Data point term sent to Coder	System	02 Oct 2020 21:20:55
User entered 'seafood allergy (itching)'	(b) (4), (b) (6)	02 Oct 2020 21:20:07

**US3322409**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered 'UN UNK 2013' reason for change:		02 Oct 2020 21:20:36
Data Entry Error		
User entered '2 Oct 2020'		02 Oct 2020 21:20:07

**US3322409**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered '0'		02 Oct 2020 21:20:07



**US3322409**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 20:57:56
User entered 'Yes (Y)'		02 Oct 2020 21:20:07

**US3322409**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered empty.		02 Oct 2020 21:20:07

**US3322409**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered '0'		02 Oct 2020 21:20:07

**US3322409**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered 'Jan 2013'	System	02 Oct 2020 21:20:36
User entered 'Oct 2020'	System	02 Oct 2020 21:20:07

**US3322409**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered '2013'	System	02 Oct 2020 21:20:36
User entered '2020'	System	02 Oct 2020 21:20:07

**US3322409**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered empty.	System	02 Oct 2020 21:20:07

**US3322409**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered empty.	System	02 Oct 2020 21:20:07

US3322409

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:19:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 21:21:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 21:21:45
Data point term sent to Coder	System	02 Oct 2020 21:20:57
User entered 'headaches'	(b) (4), (b) (6)	02 Oct 2020 21:20:24



**US3322409**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered 'UN UNK 2016'		02 Oct 2020 21:20:24

**US3322409**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered '0'		02 Oct 2020 21:20:24

**US3322409**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered 'Yes (Y)'		02 Oct 2020 21:20:24

**US3322409**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered empty.		02 Oct 2020 21:20:24

**US3322409**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered '0'		02 Oct 2020 21:20:24

**US3322409**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered 'Jan 2016'	System	02 Oct 2020 21:20:24

**US3322409**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered '2016'	System	02 Oct 2020 21:20:24

**US3322409**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered empty.	System	02 Oct 2020 21:20:24



**US3322409**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered empty.	System	02 Oct 2020 21:20:24

US3322409

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:19:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 21:22:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 21:22:47
Data point term sent to Coder	System	02 Oct 2020 21:21:58
User entered 'exercise induced muscle aches'	(b) (4), (b) (6)	02 Oct 2020 21:21:01

**US3322409**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered 'UN UNK 2016'		02 Oct 2020 21:21:01

**US3322409**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered '0'		02 Oct 2020 21:21:01

**US3322409**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered 'Yes (Y)'		02 Oct 2020 21:21:01

**US3322409**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered empty.		02 Oct 2020 21:21:01

**US3322409**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered '0'		02 Oct 2020 21:21:01

**US3322409**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered 'Jan 2016'	System	02 Oct 2020 21:21:01



**US3322409**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered '2016'	System	02 Oct 2020 21:21:01

**US3322409**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered empty.	System	02 Oct 2020 21:21:01

**US3322409**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered empty.	System	02 Oct 2020 21:21:01

US3322409

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:19:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
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)	02 Oct 2020 21:22:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 21:22:47
Data point term sent to Coder	System	02 Oct 2020 21:21:58
User entered 'Facial acne'	(b) (4), (b) (6)	02 Oct 2020 21:21:26

**US3322409**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered 'UN Jan 2020'		02 Oct 2020 21:21:26

**US3322409**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered '0'		02 Oct 2020 21:21:26

**US3322409**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered 'Yes (Y)'		02 Oct 2020 21:21:26

**US3322409**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered empty.		02 Oct 2020 21:21:26



**US3322409**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:56
User entered '0'		02 Oct 2020 21:21:26

US3322409

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:19:05

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered 'Jan 2020'	System	02 Oct 2020 21:21:26

**US3322409**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered '2020'	System	02 Oct 2020 21:21:26

**US3322409**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered empty.	System	02 Oct 2020 21:21:26

**US3322409**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered empty.	System	02 Oct 2020 21:21:26

**US3322409**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:59:26
User entered 'Yes (Y)'		02 Oct 2020 21:22:12

US3322409

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:59:26
User entered '2 Oct 2020'		02 Oct 2020 21:22:12

**US3322409**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:59:26
User entered '13:10' reason for change: Data Entry Error		02 Oct 2020 21:29:28
User entered '13:19'		02 Oct 2020 21:22:12



**US3322409**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered '2 Oct 2020 13:10'	System	02 Oct 2020 21:29:28
User entered '2 Oct 2020 13:19'	System	02 Oct 2020 21:22:12

US3322409

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:59:26
User entered '62' in		02 Oct 2020 21:22:12
DataPoint set to visible.	System	02 Oct 2020 19:51:48

US3322409

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:59:26
User entered '115' lb		02 Oct 2020 21:22:12
DataPoint set to visible.	System	02 Oct 2020 19:51:48

US3322409

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered '21.07775'	System	02 Oct 2020 21:22:12
DataPoint set to visible.	System	02 Oct 2020 19:51:48

**US3322409**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered 'kg/m2'	System	02 Oct 2020 21:22:12
DataPoint set to visible.	System	02 Oct 2020 19:51:48

US3322409

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:59:26
User entered missing code ND - Not Done.		02 Oct 2020 21:22:12

**US3322409**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:59:26
User entered empty.		02 Oct 2020 21:22:12

**US3322409**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:59:26
User entered empty.		02 Oct 2020 21:22:12



**US3322409**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:59:26
User entered missing code ND - Not Done.		02 Oct 2020 21:22:12

**US3322409**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered 'bpm'	System	02 Oct 2020 21:22:12

US3322409

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:59:26
User entered missing code ND - Not Done.		02 Oct 2020 21:22:12

US3322409

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered 'breaths/min'	System	02 Oct 2020 21:22:12

**US3322409**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:59:26
User entered missing code ND - Not Done.		02 Oct 2020 21:22:12

US3322409

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered 'mmHg'	System	02 Oct 2020 21:22:12

US3322409

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:59:26
User entered missing code ND - Not Done.		02 Oct 2020 21:22:12

US3322409

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered 'mmHg'	System	02 Oct 2020 21:22:12



US3322409

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58

US3322409

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58

US3322409

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:02
User entered 'Yes (Y)'		02 Oct 2020 21:22:25

**US3322409**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:19:05**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:02
User entered '2 Oct 2020'		02 Oct 2020 21:22:25

**US3322409**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:19:05**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:36
User entered '2 Oct 2020'		02 Oct 2020 21:22:39

US3322409

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:19:05

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:36
User closed query 'Per CDM: Please consider adding contraceptive method under CM form or clarify otherwise. Thank you!' (Site from DM).		20 Nov 2020 15:07:10
Query 'Per CDM: Please consider adding contraceptive method under CM form or clarify otherwise. Thank you!' answered with 'Contraceptive is the barrier method, which is not a CM. Please clarify. ' (Site from DM).	Blessing Felix-Okoroji (b) (4)	19 Nov 2020 14:36:42
User opened query 'Per CDM: Please consider adding contraceptive method under CM form or clarify otherwise. Thank you!' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 12:37:05
User entered 'Yes (Y)'		02 Oct 2020 21:22:39

**US3322409**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:19:05**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:36
User entered empty.		02 Oct 2020 21:22:39

**US3322409**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:19:05**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:36
User entered empty.		02 Oct 2020 21:22:39



**US3322409**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:36
User entered empty.		02 Oct 2020 21:22:39

**US3322409**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:19:05**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:36
User entered '0'		02 Oct 2020 21:22:39

US3322409

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:36
User entered empty.		02 Oct 2020 21:22:39

**US3322409**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:19:05**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:00:36
User entered '0'		02 Oct 2020 21:22:39

US3322409

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:45
User entered 'Yes (Y)'		02 Oct 2020 21:23:00

**US3322409**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:45
User entered '2 Oct 2020'		02 Oct 2020 21:23:00

**US3322409**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:45
User entered 'Urine (URINE)'		02 Oct 2020 21:23:00

US3322409

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:45
User entered 'Negative (NEGATIVE)'		02 Oct 2020 21:23:00



**US3322409**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:45
User entered 'No (N)'		02 Oct 2020 21:23:00

**US3322409**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:00:45
User entered empty.		02 Oct 2020 21:23:00

**US3322409**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:00:45
User entered empty.		02 Oct 2020 21:23:00

**US3322409**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User entered empty.	System	02 Oct 2020 21:23:00

US3322409

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:27
User entered 'Yes (Y)'		02 Oct 2020 21:24:38

US3322409

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered 'No (N)'		02 Oct 2020 21:24:38

US3322409

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered 'No (N)'		02 Oct 2020 21:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered 'No (N)'		02 Oct 2020 21:24:38



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Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered 'No (N)'		02 Oct 2020 21:24:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered 'No (N)'		02 Oct 2020 21:24:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered 'No (N)'		02 Oct 2020 21:24:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered 'No (N)'		02 Oct 2020 21:24:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered 'No (N)'		02 Oct 2020 21:24:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered 'No (N)'		02 Oct 2020 21:24:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered 'No (N)'		02 Oct 2020 21:24:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered 'Yes (Y)'		02 Oct 2020 21:24:38



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered 'research coordinator, will be back to work from next week'		02 Oct 2020 21:24:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 21:24:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered '0'		02 Oct 2020 21:24:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered '0'		02 Oct 2020 21:24:38

US3322409

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:01:54
User entered '0'		02 Oct 2020 21:24:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered '0'		02 Oct 2020 21:24:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User entered 'I'		02 Oct 2020 21:24:38

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered '1' reason for change: Data Entry Error	(b) (4) Blessing Felix-Okoroji	05 Oct 2020 17:16:18
User entered '0'	(b) (4), (b) (6)	02 Oct 2020 21:24:38



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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:19:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:11:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:01:54
User closed query 'Other specified is provided for Location and Living Circumstances Risk, but OTHER is not selected for Location and Living Circumstances Risk. Please reconcile.' (Site from System).	System	05 Oct 2020 17:16:18
User opened query 'Other specified is provided for Location and Living Circumstances Risk, but OTHER is not selected for Location and Living Circumstances Risk. Please reconcile.' (Site from System).	System	02 Oct 2020 21:24:38
User entered 'Lives with boyfriend and her parents in the house. Boyfriend is nurse at high risk. Father works at restaurant. Mother is sales person at (b) (6) . PT goes to gym with friends 2x per week'	(b) (4), (b) (6)	02 Oct 2020 21:24:38

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:02:15
User entered 'Yes (Y)'		02 Oct 2020 21:25:03

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:02:15
User entered '2 Oct 2020'		02 Oct 2020 21:25:03

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:02:15
User entered 'Clinic (Clinic)'		02 Oct 2020 21:25:03

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered 'VISIT1'	System	02 Oct 2020 21:25:03

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:19
User entered '02 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Oct 2020 19:17:50

US3322409

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:19:05

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:19
User entered '116334'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Oct 2020 19:17:50

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:19
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	02 Oct 2020 19:17:50



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:19:05

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)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:03:19
User entered 'No (N)'		02 Oct 2020 21:27:09

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:19:05

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)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:19
User entered 'No (N)'		02 Oct 2020 21:27:09

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:19
User entered 'No (N)'		02 Oct 2020 21:27:09

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:19:05**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:19
User entered 'No (N)'		02 Oct 2020 21:27:09

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:19:05**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:19
User entered 'No (N)'		02 Oct 2020 21:27:09

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:19:05**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:19
User entered 'No (N)'		02 Oct 2020 21:27:09
DataPoint set to visible.	System	02 Oct 2020 19:51:43

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:19:05**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered missing code ND - Not Done.		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:19:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:05:01
User entered missing code ND - Not Done.		02 Oct 2020 21:29:06



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:19:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered missing code ND - Not Done.		02 Oct 2020 21:29:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:19:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered missing code ND - Not Done.		02 Oct 2020 21:29:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User accepted default value 'Pre-Dose (PREDOSE)'		02 Oct 2020 21:29:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered 'Yes (Y)'		02 Oct 2020 21:29:06

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered '2 Oct 2020'		02 Oct 2020 21:29:06

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered '13:19'		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered '2 Oct 2020 13:19'	System	02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered '97.3' F		02 Oct 2020 21:29:06



**US3322409**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered 'Oral (Oral)'		02 Oct 2020 21:29:06

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered empty.		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered '74'		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered 'bpm'	System	02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered '15'		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered 'breaths/min'	System	02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered '115'		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered 'mmHg'	System	02 Oct 2020 21:29:06



**US3322409**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered '73'		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered 'mmHg'	System	02 Oct 2020 21:29:06

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:19:05**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered missing code ND - Not Done.		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:19:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered missing code ND - Not Done.		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User accepted default value 'Post-Dose (POSTDOSE)'		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered 'Yes (Y)'		02 Oct 2020 21:29:06

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered '2 Oct 2020'		02 Oct 2020 21:29:06

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered '15:24'		02 Oct 2020 21:29:06



US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered '2 Oct 2020 15:24'	System	02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered '98.4' F		02 Oct 2020 21:29:06

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered 'Oral (Oral)'		02 Oct 2020 21:29:06

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered empty.		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered '78'		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered 'bpm'	System	02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered '15'		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered 'breaths/min'	System	02 Oct 2020 21:29:06



US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered '118'		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered 'mmHg'	System	02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:05:01
User entered '66'		02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered 'mmHg'	System	02 Oct 2020 21:29:06

US3322409

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:53
User entered 'No (N)'		02 Oct 2020 21:29:36

US3322409

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:53
User entered empty.		02 Oct 2020 21:29:36

US3322409

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 21:03:56
User entered 'No (N)'		02 Oct 2020 21:30:13

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:56
User entered empty.		02 Oct 2020 21:30:13



US3322409

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:56
User entered empty.		02 Oct 2020 21:30:13

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:56
User entered empty.		02 Oct 2020 21:30:13

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:56
User entered empty.		02 Oct 2020 21:30:13

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:56
User entered empty.		02 Oct 2020 21:30:13

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:03:56
User entered empty.		02 Oct 2020 21:30:13

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered empty.	System	02 Oct 2020 21:30:13

US3322409

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	02 Oct 2020 19:52:10

US3322409

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered empty.	Frances Saubon (b) (4) (b) (4)	02 Oct 2020 19:52:10



US3322409

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

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)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered empty.	Frances Saubon (b) (4)	02 Oct 2020 19:52:10

US3322409

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 19:52:10

US3322409

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '2 Oct 2020'	Frances Saubon (b) (4) (b) (4)	02 Oct 2020 19:52:10

US3322409

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered '14:25' reason for change: Data Entry Error		02 Oct 2020 21:31:07
User entered '14:48'	Frances Saubon (b) (4) (b) (4)	02 Oct 2020 19:52:10

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:19:05**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered '2 Oct 2020 14:25'	System	02 Oct 2020 21:31:07
User entered '2 Oct 2020 14:48'	System	02 Oct 2020 19:52:10

US3322409

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:04:08
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4) (b) (4)	02 Oct 2020 19:52:10

US3322409

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
DataPoint Verified.		25 Feb 2021 21:04:08
User entered 'ONCE'	System	02 Oct 2020 19:52:10

US3322409

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 19:52:10



**US3322409**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:19:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:04:17
User entered 'Yes (Y)'		02 Oct 2020 21:32:07

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:19:05**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:04:17
User entered '2 Oct 2020'		02 Oct 2020 21:32:07

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:19:05**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:04:17
User entered '14:25'		02 Oct 2020 21:32:07

US3322409

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:19:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered '2 Oct 2020 14:25'	System	02 Oct 2020 21:32:07

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:19:05**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:04:24
User entered '2 Oct 2020'		02 Oct 2020 21:32:38

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		02 Oct 2020 21:32:38

US3322409

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:19:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:04:24
User entered 'Yes (Y)'		02 Oct 2020 21:32:38

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:19:05**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:04:24
User entered '14:20'		02 Oct 2020 21:32:38



US3322409

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:19:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered '2 Oct 2020 14:20'	System	02 Oct 2020 21:32:38

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		02 Oct 2020 21:32:38

US3322409

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:19:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:04:24
User entered 'No (N)'		02 Oct 2020 21:32:38

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:19:05**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:04:24
User entered empty.		02 Oct 2020 21:32:38

US3322409

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:19:05

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered empty.	System	02 Oct 2020 21:32:38

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:04:28
User entered 'Yes (Y)'		02 Oct 2020 21:32:42

**US3322409**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered 'I'	System	02 Oct 2020 21:32:42

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 19:52:10



US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:24:14', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '9fe4b9c3-8e3f-421e-8dd1-86fb8cd7660f' User entered 'Yes (Y)'	System	02 Oct 2020 20:24:38
	System	02 Oct 2020 20:24:38

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:24:18', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '9fe4b9c3-8e3f-421e-8dd1-86fb8cd7660f' User entered '98.4'	System	02 Oct 2020 20:24:38
	System	02 Oct 2020 20:24:38

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:24:29', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '9fe4b9c3-8e3f-421e-8dd1-86fb8cd7660f' User entered 'No (N)'	System	02 Oct 2020 20:24:38
	System	02 Oct 2020 20:24:38

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:24:34', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '9fe4b9c3-8e3f-421e-8dd1-86fb8cd7660f' User entered '02 Oct 2020 15:24'	System	02 Oct 2020 20:24:38
	System	02 Oct 2020 20:24:38

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '02 Oct 2020 15:08'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '02 Oct 2020 17:38'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:09:24', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4c7abd8b-411b-455e-b0f6-e2c52f1f3882' User entered 'Yes (Y)'	System	03 Oct 2020 02:09:38
	System	03 Oct 2020 02:09:38



US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:09:30', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4c7abd8b-411b-455e-b0f6-e2c52f1f3882' User entered '97.5'	System	03 Oct 2020 02:09:38
	System	03 Oct 2020 02:09:38

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:09:32', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4c7abd8b-411b-455e-b0f6-e2c52f1f3882'	System	03 Oct 2020 02:09:38
User entered 'No (N)'	System	03 Oct 2020 02:09:38

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:09:35', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4c7abd8b-411b-455e-b0f6-e2c52f1f3882' User entered '02 Oct 2020 21:09'	System	03 Oct 2020 02:09:38
	System	03 Oct 2020 02:09:38

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '02 Oct 2020 18:10'	System	02 Oct 2020 21:31:07
User entered '02 Oct 2020 18:33'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 2'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:01:17', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd3d0e6bb-c18a-4b15-a0c7-cac857fb3ec1' User entered 'Yes (Y)'	System	03 Oct 2020 17:01:49
	System	03 Oct 2020 17:01:49

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:01:28', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd3d0e6bb-c18a-4b15-a0c7-cac857fb3ec1' User entered '98.0'	System	03 Oct 2020 17:01:49
	System	03 Oct 2020 17:01:49



US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:01:31', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd3d0e6bb-c18a-4b15-a0c7-cac857fb3ec1' User entered 'No (N)'	System	03 Oct 2020 17:01:49
	System	03 Oct 2020 17:01:49

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:01:39', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd3d0e6bb-c18a-4b15-a0c7-cac857fb3ec1' User entered '03 Oct 2020 12:01'	System	03 Oct 2020 17:01:49
	System	03 Oct 2020 17:01:49

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 3'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:33:33', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4b63c822-ee1f-4b30-87f0-01e0899b969f' User entered 'Yes (Y)'	System	04 Oct 2020 18:34:09
	System	04 Oct 2020 18:34:09

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:33:43', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4b63c822-ee1f-4b30-87f0-01e0899b969f' User entered '98.5'	System	04 Oct 2020 18:34:09
	System	04 Oct 2020 18:34:09

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:33:52', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4b63c822-ee1f-4b30-87f0-01e0899b969f' User entered 'Yes (Y)'	System	04 Oct 2020 18:34:09
	System	04 Oct 2020 18:34:09



US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Patient has been followed up with and reported they took medication for a muscle pain. Conmed page is updated.' (Site from System).		08 Oct 2020 21:42:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:33:59', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4b63c822-ee1f-4b30-87f0-01e0899b969f' User entered '1'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 14:03:57
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	04 Oct 2020 18:34:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:33:59', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4b63c822-ee1f-4b30-87f0-01e0899b969f' User entered '1'	System	04 Oct 2020 18:34:09
User entered '1'	System	04 Oct 2020 18:34:09

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:33:59', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4b63c822-ee1f-4b30-87f0-01e0899b969f' User entered '0'	System	04 Oct 2020 18:34:09
	System	04 Oct 2020 18:34:09

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:34:07', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4b63c822-ee1f-4b30-87f0-01e0899b969f' User entered '04 Oct 2020 13:34'	System	04 Oct 2020 18:34:09
	System	04 Oct 2020 18:34:09

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 4'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:05:21', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '1d746bee-07d7-4a44-ab6d-92be55bef9fa' User entered 'Yes (Y)'	System	05 Oct 2020 17:05:44
	System	05 Oct 2020 17:05:44

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:05:30', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '1d746bee-07d7-4a44-ab6d-92be55bef9fa' User entered '97.9'	System	05 Oct 2020 17:05:44
	System	05 Oct 2020 17:05:44



US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:05:36', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '1d746bee-07d7-4a44-ab6d-92be55bef9fa' User entered 'No (N)'	System	05 Oct 2020 17:05:44
	System	05 Oct 2020 17:05:44

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:05:40', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '1d746bee-07d7-4a44-ab6d-92be55bef9fa' User entered '05 Oct 2020 12:05'	System	05 Oct 2020 17:05:44
	System	05 Oct 2020 17:05:44

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 19:52:10

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 5'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:00:33', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '1b20dba8-8d82-446f-b0b1-5e33387df061' User entered 'Yes (Y)'	System	06 Oct 2020 17:00:58
	System	06 Oct 2020 17:00:58

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:00:40', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '1b20dba8-8d82-446f-b0b1-5e33387df061' User entered '97.4'	System	06 Oct 2020 17:00:58
	System	06 Oct 2020 17:00:58

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:00:43', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '1b20dba8-8d82-446f-b0b1-5e33387df061' User entered 'No (N)'	System	06 Oct 2020 17:00:58
	System	06 Oct 2020 17:00:58



**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:00:47', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '1b20dba8-8d82-446f-b0b1-5e33387df061' User entered '06 Oct 2020 12:00'	System	06 Oct 2020 17:00:58
	System	06 Oct 2020 17:00:58

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 6'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:07:47', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '31150a88-2672-4528-87d4-7fb35180ea6e' User entered 'Yes (Y)'	System	07 Oct 2020 21:08:02
	System	07 Oct 2020 21:08:02

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:07:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '31150a88-2672-4528-87d4-7fb35180ea6e' User entered '98.9'	System	07 Oct 2020 21:08:02
	System	07 Oct 2020 21:08:02

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:07:57', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '31150a88-2672-4528-87d4-7fb35180ea6e' User entered 'No (N)'	System	07 Oct 2020 21:08:02
	System	07 Oct 2020 21:08:02

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:08:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '31150a88-2672-4528-87d4-7fb35180ea6e' User entered '07 Oct 2020 16:08'	System	07 Oct 2020 21:08:02
	System	07 Oct 2020 21:08:02



US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 7'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:01:43', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '067168dd-1858-4cb7-93a9-c9d2cc3a410e' User entered 'Yes (Y)'	System	08 Oct 2020 17:02:44
	System	08 Oct 2020 17:02:44

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:01:47', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '067168dd-1858-4cb7-93a9-c9d2cc3a410e' User entered '97.1'	System	08 Oct 2020 17:02:44
	System	08 Oct 2020 17:02:44

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:01:51', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '067168dd-1858-4cb7-93a9-c9d2cc3a410e' User entered 'No (N)'	System	08 Oct 2020 17:02:44
	System	08 Oct 2020 17:02:44

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:19:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:01:53', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '067168dd-1858-4cb7-93a9-c9d2cc3a410e' User entered '08 Oct 2020 12:01'	System	08 Oct 2020 17:02:44
	System	08 Oct 2020 17:02:44

US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 19:52:10



US3322409

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:24:43', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '1c5c46f8-d098-4b0e-bf42-e6ee2fdd08b0' User entered 'None (1)'	System	02 Oct 2020 20:25:21
	System	02 Oct 2020 20:25:21

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:25:04', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '1c5c46f8-d098-4b0e-bf42-e6ee2fdd08b0' User entered 'No (N)'	System	02 Oct 2020 20:25:21
	System	02 Oct 2020 20:25:21

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:25:07', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '1c5c46f8-d098-4b0e-bf42-e6ee2fdd08b0' User entered 'No (N)'	System	02 Oct 2020 20:25:21
	System	02 Oct 2020 20:25:21

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:25:13', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '1c5c46f8-d098-4b0e-bf42-e6ee2fdd08b0'	System	02 Oct 2020 20:25:21
User entered 'None (1)'	System	02 Oct 2020 20:25:21

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:25:16', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '1c5c46f8-d098-4b0e-bf42-e6ee2fdd08b0' User entered '02 Oct 2020 15:25'	System	02 Oct 2020 20:25:21
	System	02 Oct 2020 20:25:21

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '02 Oct 2020 15:08'	System	02 Oct 2020 19:52:10



US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '02 Oct 2020 17:38'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:09:43', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '50d4de1e-35cc-4b95-b072-a74729307e0e' User entered 'None (1)'	System	03 Oct 2020 02:09:53
	System	03 Oct 2020 02:09:53

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:09:45', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '50d4de1e-35cc-4b95-b072-a74729307e0e' User entered 'No (N)'	System	03 Oct 2020 02:09:53
	System	03 Oct 2020 02:09:53

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:09:47', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '50d4de1e-35cc-4b95-b072-a74729307e0e' User entered 'No (N)'	System	03 Oct 2020 02:09:53
	System	03 Oct 2020 02:09:53

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:09:49', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '50d4de1e-35cc-4b95-b072-a74729307e0e' User entered 'None (1)'	System	03 Oct 2020 02:09:53
	System	03 Oct 2020 02:09:53

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:09:52', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '50d4de1e-35cc-4b95-b072-a74729307e0e' User entered '02 Oct 2020 21:09'	System	03 Oct 2020 02:09:53
	System	03 Oct 2020 02:09:53

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '02 Oct 2020 18:10'	System	02 Oct 2020 21:31:07
User entered '02 Oct 2020 18:33'	System	02 Oct 2020 19:52:10



**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 2'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:01:45', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b0d0735f-3509-4c59-b41c-bcfa7766d4b1' User entered 'None (1)'	System	03 Oct 2020 17:02:07
	System	03 Oct 2020 17:02:07

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:01:49', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b0d0735f-3509-4c59-b41c-bcfa7766d4b1' User entered 'No (N)'	System	03 Oct 2020 17:02:07
	System	03 Oct 2020 17:02:07

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:01:51', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b0d0735f-3509-4c59-b41c-bcfa7766d4b1' User entered 'No (N)'	System	03 Oct 2020 17:02:07
	System	03 Oct 2020 17:02:07

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:01:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b0d0735f-3509-4c59-b41c-bcfa7766d4b1' User entered 'None (1)'	System	03 Oct 2020 17:02:07
	System	03 Oct 2020 17:02:07

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:02:02', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b0d0735f-3509-4c59-b41c-bcfa7766d4b1' User entered '03 Oct 2020 12:02'	System	03 Oct 2020 17:02:07
	System	03 Oct 2020 17:02:07

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 19:52:10



**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 3'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:34:27', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '8da8b8cd-1a6c-4c9e-9c0f-91282be3f394'	System	04 Oct 2020 18:34:43
User entered 'None (1)'	System	04 Oct 2020 18:34:43

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:19:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:34:31', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '8da8b8cd-1a6c-4c9e-9c0f-91282be3f394' User entered 'No (N)'	System	04 Oct 2020 18:34:43
	System	04 Oct 2020 18:34:43

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:34:34', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '8da8b8cd-1a6c-4c9e-9c0f-91282be3f394'	System	04 Oct 2020 18:34:43
User entered 'No (N)'	System	04 Oct 2020 18:34:43

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:34:39', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '8da8b8cd-1a6c-4c9e-9c0f-91282be3f394'	System	04 Oct 2020 18:34:43
User entered 'None (1)'	System	04 Oct 2020 18:34:43

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:19:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:34:42', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '8da8b8cd-1a6c-4c9e-9c0f-91282be3f394'	System	04 Oct 2020 18:34:43
User entered '04 Oct 2020 13:34'	System	04 Oct 2020 18:34:43

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 19:52:10



**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 4'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:05:43', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0320a8d2-1de7-4921-bf3a-8f24bddec407' User entered 'None (1)'	System	05 Oct 2020 17:06:02
	System	05 Oct 2020 17:06:02

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:05:46', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0320a8d2-1de7-4921-bf3a-8f24bddec407' User entered 'No (N)'	System	05 Oct 2020 17:06:02
	System	05 Oct 2020 17:06:02

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:05:48', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0320a8d2-1de7-4921-bf3a-8f24bddec407' User entered 'No (N)'	System	05 Oct 2020 17:06:02
	System	05 Oct 2020 17:06:02

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:05:56', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0320a8d2-1de7-4921-bf3a-8f24bddec407'	System	05 Oct 2020 17:06:02
User entered 'None (1)'	System	05 Oct 2020 17:06:02

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:05:58', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0320a8d2-1de7-4921-bf3a-8f24bddec407' User entered '05 Oct 2020 12:05'	System	05 Oct 2020 17:06:02
	System	05 Oct 2020 17:06:02

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 19:52:10



**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 5'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:00:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '506199f7-cd43-482c-9dce-ff732673a696'	System	06 Oct 2020 17:01:20
User entered 'None (1)'	System	06 Oct 2020 17:01:20

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:19:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:00:55', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '506199f7-cd43-482c-9dce-ff732673a696' User entered 'No (N)'	System	06 Oct 2020 17:01:20
	System	06 Oct 2020 17:01:20

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:00:57', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '506199f7-cd43-482c-9dce-ff732673a696'	System	06 Oct 2020 17:01:20
User entered 'No (N)'	System	06 Oct 2020 17:01:20

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:00:58', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '506199f7-cd43-482c-9dce-ff732673a696'	System	06 Oct 2020 17:01:20
User entered 'None (1)'	System	06 Oct 2020 17:01:20

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:01:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '506199f7-cd43-482c-9dce-ff732673a696' User entered '06 Oct 2020 12:01'	System	06 Oct 2020 17:01:20
	System	06 Oct 2020 17:01:20

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 19:52:10



**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 6'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:08:03', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'a6629954-7b93-46f5-9ed1-916554fb35f7'	System	07 Oct 2020 21:08:13
User entered 'None (1)'	System	07 Oct 2020 21:08:13

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:19:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:08:04', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'a6629954-7b93-46f5-9ed1-916554fb35f7' User entered 'No (N)'	System	07 Oct 2020 21:08:13
	System	07 Oct 2020 21:08:13

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:08:07', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'a6629954-7b93-46f5-9ed1-916554fb35f7' User entered 'No (N)'	System	07 Oct 2020 21:08:13
	System	07 Oct 2020 21:08:13

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:08:08', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'a6629954-7b93-46f5-9ed1-916554fb35f7'	System	07 Oct 2020 21:08:13
User entered 'None (1)'	System	07 Oct 2020 21:08:13

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:19:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:08:11', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'a6629954-7b93-46f5-9ed1-916554fb35f7' User entered '07 Oct 2020 16:08'	System	07 Oct 2020 21:08:13
	System	07 Oct 2020 21:08:13

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 19:52:10



**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 7'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:01:57', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '7307094e-62a8-4c08-8b01-b1e8951c5954' User entered 'None (1)'	System	08 Oct 2020 17:02:52
	System	08 Oct 2020 17:02:52

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:19:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:01:58', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '7307094e-62a8-4c08-8b01-b1e8951c5954' User entered 'No (N)'	System	08 Oct 2020 17:02:52
	System	08 Oct 2020 17:02:52

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:02:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '7307094e-62a8-4c08-8b01-b1e8951c5954' User entered 'No (N)'	System	08 Oct 2020 17:02:52
	System	08 Oct 2020 17:02:52

US3322409

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:02:01', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '7307094e-62a8-4c08-8b01-b1e8951c5954' User entered 'None (1)'	System	08 Oct 2020 17:02:52
	System	08 Oct 2020 17:02:52

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:02:03', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '7307094e-62a8-4c08-8b01-b1e8951c5954' User entered '08 Oct 2020 12:02'	System	08 Oct 2020 17:02:52
	System	08 Oct 2020 17:02:52

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 19:52:10



**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:25:35', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'bf61b28d-8f46-483f-a013-aaa10d88e084' User entered 'None (0)'	System	02 Oct 2020 20:25:57
	System	02 Oct 2020 20:25:57

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:25:39', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'bf61b28d-8f46-483f-a013-aaa10d88e084' User entered 'None (0)'	System	02 Oct 2020 20:25:57
	System	02 Oct 2020 20:25:57

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:25:42', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'bf61b28d-8f46-483f-a013-aaa10d88e084' User entered 'None (0)'	System	02 Oct 2020 20:25:57
	System	02 Oct 2020 20:25:57

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:25:44', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'bf61b28d-8f46-483f-a013-aaa10d88e084' User entered 'None (0)'	System	02 Oct 2020 20:25:57
	System	02 Oct 2020 20:25:57

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:25:46', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'bf61b28d-8f46-483f-a013-aaa10d88e084' User entered 'None (0)'	System	02 Oct 2020 20:25:57
	System	02 Oct 2020 20:25:57

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:25:47', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'bf61b28d-8f46-483f-a013-aaa10d88e084' User entered 'None (0)'	System	02 Oct 2020 20:25:57
	System	02 Oct 2020 20:25:57



US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:25:52', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'bf61b28d-8f46-483f-a013-aaa10d88e084'	System	02 Oct 2020 20:25:57
User entered 'No (N)'	System	02 Oct 2020 20:25:57

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T15:25:55', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'bf61b28d-8f46-483f-a013-aaa10d88e084' User entered '02 Oct 2020 15:25'	System	02 Oct 2020 20:25:57
	System	02 Oct 2020 20:25:57

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '02 Oct 2020 15:08'	System	02 Oct 2020 19:52:10

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '02 Oct 2020 17:38'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:09:58', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '62f2ae75-be29-477e-8966-b554f7006b0c' User entered 'None (0)'	System	03 Oct 2020 02:10:20
	System	03 Oct 2020 02:10:20

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:10:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '62f2ae75-be29-477e-8966-b554f7006b0c' User entered 'None (0)'	System	03 Oct 2020 02:10:20
	System	03 Oct 2020 02:10:20

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:10:02', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '62f2ae75-be29-477e-8966-b554f7006b0c' User entered 'None (0)'	System	03 Oct 2020 02:10:20
	System	03 Oct 2020 02:10:20



US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:10:03', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '62f2ae75-be29-477e-8966-b554f7006b0c' User entered 'None (0)'	System	03 Oct 2020 02:10:20
	System	03 Oct 2020 02:10:20

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:10:05', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '62f2ae75-be29-477e-8966-b554f7006b0c' User entered 'None (0)'	System	03 Oct 2020 02:10:20
	System	03 Oct 2020 02:10:20

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:10:06', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '62f2ae75-be29-477e-8966-b554f7006b0c' User entered 'None (0)'	System	03 Oct 2020 02:10:20
	System	03 Oct 2020 02:10:20

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:10:13', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '62f2ae75-be29-477e-8966-b554f7006b0c' User entered 'No (N)'	System	03 Oct 2020 02:10:20
	System	03 Oct 2020 02:10:20

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-02T21:10:15', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '62f2ae75-be29-477e-8966-b554f7006b0c' User entered '02 Oct 2020 21:10'	System	03 Oct 2020 02:10:20
	System	03 Oct 2020 02:10:20

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '02 Oct 2020 18:10'	System	02 Oct 2020 21:31:07
User entered '02 Oct 2020 18:33'	System	02 Oct 2020 19:52:10

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 2'	System	02 Oct 2020 19:52:10



US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:02:07', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '047232dd-8904-45a8-bc20-565a82341a02' User entered 'None (0)'	System	03 Oct 2020 17:02:31
	System	03 Oct 2020 17:02:31

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:02:08', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '047232dd-8904-45a8-bc20-565a82341a02'	System	03 Oct 2020 17:02:31
User entered 'None (0)'	System	03 Oct 2020 17:02:31

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:02:12', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '047232dd-8904-45a8-bc20-565a82341a02' User entered 'None (0)'	System	03 Oct 2020 17:02:31
	System	03 Oct 2020 17:02:31

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:02:14', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '047232dd-8904-45a8-bc20-565a82341a02' User entered 'None (0)'	System	03 Oct 2020 17:02:31
	System	03 Oct 2020 17:02:31

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:02:16', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '047232dd-8904-45a8-bc20-565a82341a02' User entered 'None (0)'	System	03 Oct 2020 17:02:31
	System	03 Oct 2020 17:02:31

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:02:17', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '047232dd-8904-45a8-bc20-565a82341a02'	System	03 Oct 2020 17:02:31
User entered 'None (0)'	System	03 Oct 2020 17:02:31

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:02:21', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '047232dd-8904-45a8-bc20-565a82341a02' User entered 'No (N)'	System	03 Oct 2020 17:02:31
	System	03 Oct 2020 17:02:31

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-03T12:02:25', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '047232dd-8904-45a8-bc20-565a82341a02' User entered '03 Oct 2020 12:02'	System	03 Oct 2020 17:02:31
	System	03 Oct 2020 17:02:31



**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 19:52:10

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 3'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:35:13', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5940bfb4-269e-40fb-970f-7c5cb237bcd'	System	04 Oct 2020 18:35:57
User entered 'No interference with activity (1)'	System	04 Oct 2020 18:35:57

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:35:17', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5940bfb4-269e-40fb-970f-7c5cb237bcd'	System	04 Oct 2020 18:35:57
User entered 'None (0)'	System	04 Oct 2020 18:35:57

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:35:32', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5940bfb4-269e-40fb-970f-7c5cb237bcd'	System	04 Oct 2020 18:35:57
User entered 'Some interference with activity (2)'	System	04 Oct 2020 18:35:57

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:35:37', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5940bfb4-269e-40fb-970f-7c5cb237bcd'	System	04 Oct 2020 18:35:57
User entered 'None (0)'	System	04 Oct 2020 18:35:57

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:35:40', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5940bfb4-269e-40fb-970f-7c5cb237bcd'	System	04 Oct 2020 18:35:57
User entered 'None (0)'	System	04 Oct 2020 18:35:57



US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:35:42', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5940bfb4-269e-40fb-970f-7c5cb237bcd'	System	04 Oct 2020 18:35:57
User entered 'None (0)'	System	04 Oct 2020 18:35:57

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:35:48', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5940bfb4-269e-40fb-970f-7c5cb237bcd'	System	04 Oct 2020 18:35:57
User entered 'No (N)'	System	04 Oct 2020 18:35:57

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-04T13:35:55', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5940bfb4-269e-40fb-970f-7c5cb237bcd'	System	04 Oct 2020 18:35:57
User entered '04 Oct 2020 13:35'	System	04 Oct 2020 18:35:57

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 19:52:10

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 4'	System	02 Oct 2020 19:52:10

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:06:02', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c44c4a3e-5cb0-40ed-ab6d-ce3c96183217' User entered 'None (0)'	System	05 Oct 2020 17:06:18
	System	05 Oct 2020 17:06:18

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:06:04', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c44c4a3e-5cb0-40ed-ab6d-ce3c96183217' User entered 'None (0)'	System	05 Oct 2020 17:06:18
	System	05 Oct 2020 17:06:18



US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:06:05', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c44c4a3e-5cb0-40ed-ab6d-ce3c96183217' User entered 'None (0)'	System	05 Oct 2020 17:06:18
	System	05 Oct 2020 17:06:18

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:06:07', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c44c4a3e-5cb0-40ed-ab6d-ce3c96183217' User entered 'None (0)'	System	05 Oct 2020 17:06:18
	System	05 Oct 2020 17:06:18

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:06:09', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c44c4a3e-5cb0-40ed-ab6d-ce3c96183217' User entered 'None (0)'	System	05 Oct 2020 17:06:18
	System	05 Oct 2020 17:06:18

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:06:10', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c44c4a3e-5cb0-40ed-ab6d-ce3c96183217' User entered 'None (0)'	System	05 Oct 2020 17:06:18
	System	05 Oct 2020 17:06:18

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:06:12', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c44c4a3e-5cb0-40ed-ab6d-ce3c96183217' User entered 'No (N)'	System	05 Oct 2020 17:06:18
	System	05 Oct 2020 17:06:18

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-05T12:06:15', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c44c4a3e-5cb0-40ed-ab6d-ce3c96183217' User entered '05 Oct 2020 12:06'	System	05 Oct 2020 17:06:18
	System	05 Oct 2020 17:06:18

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 19:52:10

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 19:52:10



US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 5'	System	02 Oct 2020 19:52:10

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:01:04', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c130fe6a-6351-416e-8168-354acad08a92' User entered 'None (0)'	System	06 Oct 2020 17:01:43
	System	06 Oct 2020 17:01:43

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:01:05', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c130fe6a-6351-416e-8168-354acad08a92' User entered 'None (0)'	System	06 Oct 2020 17:01:43
	System	06 Oct 2020 17:01:43

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:01:06', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c130fe6a-6351-416e-8168-354acad08a92' User entered 'None (0)'	System	06 Oct 2020 17:01:43
	System	06 Oct 2020 17:01:43

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:01:08', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c130fe6a-6351-416e-8168-354acad08a92' User entered 'None (0)'	System	06 Oct 2020 17:01:43
	System	06 Oct 2020 17:01:43

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:01:10', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c130fe6a-6351-416e-8168-354acad08a92' User entered 'None (0)'	System	06 Oct 2020 17:01:43
	System	06 Oct 2020 17:01:43

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:01:12', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c130fe6a-6351-416e-8168-354acad08a92' User entered 'None (0)'	System	06 Oct 2020 17:01:43
	System	06 Oct 2020 17:01:43

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:01:14', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c130fe6a-6351-416e-8168-354acad08a92' User entered 'No (N)'	System	06 Oct 2020 17:01:43
	System	06 Oct 2020 17:01:43



**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-06T12:01:17', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'c130fe6a-6351-416e-8168-354acad08a92' User entered '06 Oct 2020 12:01'	System	06 Oct 2020 17:01:43
	System	06 Oct 2020 17:01:43

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 19:52:10

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 6'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:08:13', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0a769d7d-a41a-477d-9e52-18ec641f5fc6' User entered 'None (0)'	System	07 Oct 2020 21:08:26
	System	07 Oct 2020 21:08:26

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:08:15', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0a769d7d-a41a-477d-9e52-18ec641f5fc6' User entered 'None (0)'	System	07 Oct 2020 21:08:26
	System	07 Oct 2020 21:08:26

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:08:16', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0a769d7d-a41a-477d-9e52-18ec641f5fc6' User entered 'None (0)'	System	07 Oct 2020 21:08:26
	System	07 Oct 2020 21:08:26

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:08:17', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0a769d7d-a41a-477d-9e52-18ec641f5fc6' User entered 'None (0)'	System	07 Oct 2020 21:08:26
	System	07 Oct 2020 21:08:26



US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:08:18', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0a769d7d-a41a-477d-9e52-18ec641f5fc6' User entered 'None (0)'	System	07 Oct 2020 21:08:26
	System	07 Oct 2020 21:08:26

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:08:20', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0a769d7d-a41a-477d-9e52-18ec641f5fc6' User entered 'None (0)'	System	07 Oct 2020 21:08:26
	System	07 Oct 2020 21:08:26

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:08:21', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0a769d7d-a41a-477d-9e52-18ec641f5fc6' User entered 'No (N)'	System	07 Oct 2020 21:08:26
	System	07 Oct 2020 21:08:26

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-07T16:08:23', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0a769d7d-a41a-477d-9e52-18ec641f5fc6' User entered '07 Oct 2020 16:08'	System	07 Oct 2020 21:08:26
	System	07 Oct 2020 21:08:26

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 19:52:10

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	02 Oct 2020 19:52:10
User entered 'Day 7'	System	02 Oct 2020 19:52:10

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:02:21', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'eb8b9b7e-77ab-4598-885e-c8429559c455' User entered 'None (0)'	System	08 Oct 2020 17:03:12
	System	08 Oct 2020 17:03:12



US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:02:22', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'eb8b9b7e-77ab-4598-885e-c8429559c455' User entered 'None (0)'	System	08 Oct 2020 17:03:12
	System	08 Oct 2020 17:03:12

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:02:23', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'eb8b9b7e-77ab-4598-885e-c8429559c455' User entered 'None (0)'	System	08 Oct 2020 17:03:12
	System	08 Oct 2020 17:03:12

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:02:25', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'eb8b9b7e-77ab-4598-885e-c8429559c455' User entered 'None (0)'	System	08 Oct 2020 17:03:12
	System	08 Oct 2020 17:03:12

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:02:26', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'eb8b9b7e-77ab-4598-885e-c8429559c455' User entered 'None (0)'	System	08 Oct 2020 17:03:12
	System	08 Oct 2020 17:03:12

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:02:27', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'eb8b9b7e-77ab-4598-885e-c8429559c455' User entered 'None (0)'	System	08 Oct 2020 17:03:12
	System	08 Oct 2020 17:03:12

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:02:29', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'eb8b9b7e-77ab-4598-885e-c8429559c455'	System	08 Oct 2020 17:03:12
User entered 'No (N)'	System	08 Oct 2020 17:03:12

US3322409

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-10-08T12:02:31', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'eb8b9b7e-77ab-4598-885e-c8429559c455' User entered '08 Oct 2020 12:02'	System	08 Oct 2020 17:03:12
	System	08 Oct 2020 17:03:12

**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 19:52:10



**US3322409**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 19:52:10

**US3322409**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:10:46
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	09 Oct 2020 20:42:35

**US3322409**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:10:46
User entered '9 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	09 Oct 2020 20:42:35

US3322409

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:10:46
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	09 Oct 2020 20:42:35

US3322409

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:10:46
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Oct 2020 20:42:35

US3322409

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:10:49
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	09 Oct 2020 20:42:46

**US3322409**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered 'I'	System	09 Oct 2020 20:42:46

**US3322409**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:11:02
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 20:11:08



**US3322409**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:11:02
User entered '16 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 20:11:08

US3322409

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:11:02
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 20:11:08

US3322409

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:11:02
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 20:11:08

US3322409

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:11:08
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Oct 2020 20:11:15

**US3322409**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 15:42:34
User entered 'I'	System	16 Oct 2020 20:11:15

**US3322409**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:11:30
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	23 Oct 2020 19:11:25

US3322409

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:11:30
User entered '23 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 19:11:25

US3322409

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:11:30
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 19:11:25



US3322409

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:11:30
User entered empty.	Elisa Moralez (b) (4)	23 Oct 2020 19:11:25

US3322409

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:04
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:11:40
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	23 Oct 2020 19:11:28

**US3322409**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:24:04
User entered 'I'	System	23 Oct 2020 19:11:28

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:12:07
User entered 'Yes (Y)'	Moez Talpur (b) (4)	06 Nov 2020 14:50:39

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:12:07
User entered '5 Nov 2020'	Moez Talpur (b) (4)	06 Nov 2020 14:50:39

US3322409

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:19:05

[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 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:12:07
User entered 'Clinic (Clinic)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:50:39

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'VISIT2'	System	06 Nov 2020 14:50:39

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User accepted default value 'Pre-Dose (PREDOSE)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57



US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered '5 Nov 2020'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered '15:30'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered '5 Nov 2020 15:30'	System	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered '98.0' F	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered 'Oral (Oral)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered empty.	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered '75'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57



US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'bpm'	System	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered '14'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'breaths/min'	System	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered '122'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'mmHg'	System	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered '83'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'mmHg'	System	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User accepted default value 'Post-Dose (POSTDOSE)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57



US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered '5 Nov 2020'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered '17:18'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered '5 Nov 2020 17:18'	System	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered '99.1' F	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered 'Oral (Oral)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered empty.	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered '64'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57



US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'bpm'	System	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered '14'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'breaths/min'	System	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered '116'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'mmHg'	System	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:14:40
User entered '80'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'mmHg'	System	06 Nov 2020 14:52:57

US3322409

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:04
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:53:10



US3322409

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:04
User entered '5 Nov 2020'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:53:10

US3322409

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:30
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:54:22

US3322409

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:30
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).		12 Nov 2020 15:01:46
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).	Frances Saubon (b) (4) (b) (4)	11 Nov 2020 19:04:40
User entered '05 Nov 2020' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	11 Nov 2020 19:04:34
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).	(b) (4), (b) (6)	11 Nov 2020 18:30:17
User entered '5 Nov 2020'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:54:22

US3322409

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:30
User entered 'Urine (URINE)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:54:22

US3322409

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:30
User entered 'Negative (NEGATIVE)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:54:22

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:30
User entered 'No (N)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:54:22

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:30
User entered empty.	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:54:22

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:30
User entered empty.	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:54:22



**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered empty.	System	06 Nov 2020 14:54:22

US3322409

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:15:43
User entered 'Yes (Y)'	Frances Saubon (b) (4)	05 Nov 2020 22:59:32

US3322409

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:15:43
User entered empty.	Frances Saubon (b) (4)	05 Nov 2020 22:59:32

US3322409

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:15:43
User entered empty.	Frances Saubon (b) (4)	05 Nov 2020 22:59:32

US3322409

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'MRNA-1273 OR PLACEBO'	System	05 Nov 2020 22:59:32

US3322409

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:15:43
User entered '05 Nov 2020'	Frances Saubon (b) (4)	05 Nov 2020 22:59:32

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:19:05**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:15:43
User entered '16:48'	Frances Saubon (b) (4)	05 Nov 2020 22:59:32

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:19:05**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered '05 Nov 2020 16:48'	System	05 Nov 2020 22:59:32



US3322409

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:43
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4) (b) (4)	05 Nov 2020 22:59:32

US3322409

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
DataPoint Verified.		25 Feb 2021 21:15:43
User entered 'ONCE'	System	05 Nov 2020 22:59:32

US3322409

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'INTRAMUSCULAR'	System	05 Nov 2020 22:59:32

US3322409

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:19:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:51
User entered 'Yes (Y)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:54:41

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:19:05**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:51
User entered '5 Nov 2020'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:54:41

US3322409

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:19:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:51
User entered '16:30'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:54:41

US3322409

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:19:05

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered '5 Nov 2020 16:30'	System	06 Nov 2020 14:54:41

US3322409

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:19:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:57
User entered '5 Nov 2020'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:55:02



**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:55:02

US3322409

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:19:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:15:57
User entered 'Yes (Y)'	Moez Talpur (b) (4)	06 Nov 2020 14:55:02

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:57
User entered '16:25'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:55:02

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered '5 Nov 2020 16:25'	System	06 Nov 2020 14:55:02

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:55:02

US3322409

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:19:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:57
User entered 'No (N)'	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:55:02

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:15:57
User entered empty.	Moez Talpur (b) (4) (b) (4)	06 Nov 2020 14:55:02

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered empty.	System	06 Nov 2020 14:55:02



US3322409

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:16:00
User entered 'Yes (Y)'	Moez Talpur (b) (4)	06 Nov 2020 14:55:15

**US3322409**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'I'	System	06 Nov 2020 14:55:15

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:19:10', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '9c316900-5499-43b9-b43c-27046e390821' User entered 'Yes (Y)'	System	05 Nov 2020 23:19:29
	System	05 Nov 2020 23:19:29

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:19:14', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '9c316900-5499-43b9-b43c-27046e390821' User entered '99.1'	System	05 Nov 2020 23:19:29
	System	05 Nov 2020 23:19:29

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:19:23', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '9c316900-5499-43b9-b43c-27046e390821' User entered 'No (N)'	System	05 Nov 2020 23:19:29
	System	05 Nov 2020 23:19:29

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:19:27', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '9c316900-5499-43b9-b43c-27046e390821' User entered '05 Nov 2020 17:19'	System	05 Nov 2020 23:19:29
	System	05 Nov 2020 23:19:29

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Nov 2020 17:08'	System	05 Nov 2020 22:59:32



US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Nov 2020 19:38'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 1, after vaccination (at home)'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:57:36', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'cf50b883-5862-453b-8f24-2a6704db203d' User entered 'Yes (Y)'	System	06 Nov 2020 04:57:53
	System	06 Nov 2020 04:57:53

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:57:43', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'cf50b883-5862-453b-8f24-2a6704db203d' User entered '98.9'	System	06 Nov 2020 04:57:53
	System	06 Nov 2020 04:57:53

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:57:45', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'cf50b883-5862-453b-8f24-2a6704db203d'	System	06 Nov 2020 04:57:53
User entered 'No (N)'	System	06 Nov 2020 04:57:53

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:57:48', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'cf50b883-5862-453b-8f24-2a6704db203d' User entered '05 Nov 2020 22:57'	System	06 Nov 2020 04:57:53
	System	06 Nov 2020 04:57:53

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Nov 2020 20:33'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '06 Nov 2020 11:59'	System	05 Nov 2020 22:59:32



US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 2'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:00:41', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b772269a-1445-4d08-9503-11938fa8100c' User entered 'Yes (Y)'	System	06 Nov 2020 18:01:16
	System	06 Nov 2020 18:01:16

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:00:45', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b772269a-1445-4d08-9503-11938fa8100c' User entered '97.1'	System	06 Nov 2020 18:01:16
	System	06 Nov 2020 18:01:16

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:00:49', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b772269a-1445-4d08-9503-11938fa8100c' User entered 'No (N)'	System	06 Nov 2020 18:01:16
	System	06 Nov 2020 18:01:16

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:19:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:00:51', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b772269a-1445-4d08-9503-11938fa8100c' User entered '06 Nov 2020 12:00'	System	06 Nov 2020 18:01:16
	System	06 Nov 2020 18:01:16

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 3'	System	05 Nov 2020 22:59:32



US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:10:37', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '99a221fa-05e4-42e0-b2f5-90796d96c8fc' User entered 'Yes (Y)'	System	07 Nov 2020 19:10:56
	System	07 Nov 2020 19:10:56

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:10:47', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '99a221fa-05e4-42e0-b2f5-90796d96c8fc' User entered '97.8'	System	07 Nov 2020 19:10:56
	System	07 Nov 2020 19:10:56

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:10:50', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '99a221fa-05e4-42e0-b2f5-90796d96c8fc' User entered 'No (N)'	System	07 Nov 2020 19:10:56
	System	07 Nov 2020 19:10:56

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:10:52', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '99a221fa-05e4-42e0-b2f5-90796d96c8fc' User entered '07 Nov 2020 13:10'	System	07 Nov 2020 19:10:56
	System	07 Nov 2020 19:10:56

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 4'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:42:18', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '48aeeab4-c3f4-44dd-9f22-afd2ef80d6ce' User entered 'Yes (Y)'	System	08 Nov 2020 19:42:44
	System	08 Nov 2020 19:42:44



US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:42:32', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '48aeeab4-c3f4-44dd-9f22-afd2ef80d6ce' User entered '98.9'	System	08 Nov 2020 19:42:44
	System	08 Nov 2020 19:42:44

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:42:36', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '48aeeab4-c3f4-44dd-9f22-afd2ef80d6ce'	System	08 Nov 2020 19:42:44
User entered 'No (N)'	System	08 Nov 2020 19:42:44

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:42:39', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '48aeeab4-c3f4-44dd-9f22-afd2ef80d6ce' User entered '08 Nov 2020 13:42'	System	08 Nov 2020 19:42:44
	System	08 Nov 2020 19:42:44

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '08 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '09 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 5'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:01:45', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '49f10823-632d-4911-8f13-d54f29bdc46e' User entered 'Yes (Y)'	System	09 Nov 2020 18:01:56
	System	09 Nov 2020 18:01:56

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:01:49', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '49f10823-632d-4911-8f13-d54f29bdc46e' User entered '97.0'	System	09 Nov 2020 18:01:56
	System	09 Nov 2020 18:01:56



US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:01:51', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '49f10823-632d-4911-8f13-d54f29bdc46e' User entered 'No (N)'	System	09 Nov 2020 18:01:56
	System	09 Nov 2020 18:01:56

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:01:53', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '49f10823-632d-4911-8f13-d54f29bdc46e' User entered '09 Nov 2020 12:01'	System	09 Nov 2020 18:01:56
	System	09 Nov 2020 18:01:56

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '09 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '10 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 6'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:07', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '85fee2cc-3469-4beb-a185-f67b4ec325be' User entered 'Yes (Y)'	System	10 Nov 2020 18:08:18
	System	10 Nov 2020 18:08:18

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:10', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '85fee2cc-3469-4beb-a185-f67b4ec325be' User entered '99.3'	System	10 Nov 2020 18:08:18
	System	10 Nov 2020 18:08:18

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:12', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '85fee2cc-3469-4beb-a185-f67b4ec325be' User entered 'No (N)'	System	10 Nov 2020 18:08:18
	System	10 Nov 2020 18:08:18



**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:15', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '85fee2cc-3469-4beb-a185-f67b4ec325be' User entered '10 Nov 2020 12:08'	System	10 Nov 2020 18:08:18
	System	10 Nov 2020 18:08:18

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '10 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '11 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 7'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:19:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:27', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '027a15cd-f5b7-4ab6-9fea-27e5a66ef557' User entered 'Yes (Y)'	System	11 Nov 2020 18:01:40
	System	11 Nov 2020 18:01:40

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:19:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:32', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '027a15cd-f5b7-4ab6-9fea-27e5a66ef557' User entered '98.7'	System	11 Nov 2020 18:01:40
	System	11 Nov 2020 18:01:40

US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:34', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '027a15cd-f5b7-4ab6-9fea-27e5a66ef557'	System	11 Nov 2020 18:01:40
User entered 'No (N)'	System	11 Nov 2020 18:01:40

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:37', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '027a15cd-f5b7-4ab6-9fea-27e5a66ef557' User entered '11 Nov 2020 12:01'	System	11 Nov 2020 18:01:40
	System	11 Nov 2020 18:01:40



US3322409

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '11 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '12 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:19:32', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'e6b60226-3bc5-4851-a2fb-69d948b0f5c8' User entered 'None (1)'	System	05 Nov 2020 23:20:06
	System	05 Nov 2020 23:20:06

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:19:46', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'e6b60226-3bc5-4851-a2fb-69d948b0f5c8' User entered 'No (N)'	System	05 Nov 2020 23:20:06
	System	05 Nov 2020 23:20:06

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:19:56', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'e6b60226-3bc5-4851-a2fb-69d948b0f5c8' User entered 'No (N)'	System	05 Nov 2020 23:20:06
	System	05 Nov 2020 23:20:06

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:19:59', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'e6b60226-3bc5-4851-a2fb-69d948b0f5c8'	System	05 Nov 2020 23:20:06
User entered 'None (1)'	System	05 Nov 2020 23:20:06

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:20:01', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'e6b60226-3bc5-4851-a2fb-69d948b0f5c8' User entered '05 Nov 2020 17:20'	System	05 Nov 2020 23:20:06
	System	05 Nov 2020 23:20:06



**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Nov 2020 17:08'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Nov 2020 19:38'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 1, after vaccination (at home)'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:57:51', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '38d25f3f-03ac-49c5-88ab-70df2d64e4b4'	System	06 Nov 2020 04:58:02
User entered 'None (1)'	System	06 Nov 2020 04:58:02

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:57:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '38d25f3f-03ac-49c5-88ab-70df2d64e4b4' User entered 'No (N)'	System	06 Nov 2020 04:58:02
	System	06 Nov 2020 04:58:02

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:57:56', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '38d25f3f-03ac-49c5-88ab-70df2d64e4b4'	System	06 Nov 2020 04:58:02
User entered 'No (N)'	System	06 Nov 2020 04:58:02

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:57:57', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '38d25f3f-03ac-49c5-88ab-70df2d64e4b4'	System	06 Nov 2020 04:58:02
User entered 'None (1)'	System	06 Nov 2020 04:58:02

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:57:59', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '38d25f3f-03ac-49c5-88ab-70df2d64e4b4' User entered '05 Nov 2020 22:57'	System	06 Nov 2020 04:58:02
	System	06 Nov 2020 04:58:02



US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Nov 2020 20:33'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '06 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 2'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:00:55', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'ef0bc633-863d-4281-b941-2d4fd093a13d'	System	06 Nov 2020 18:01:28
User entered 'None (1)'	System	06 Nov 2020 18:01:28

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:00:57', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'ef0bc633-863d-4281-b941-2d4fd093a13d'	System	06 Nov 2020 18:01:28
User entered 'No (N)'	System	06 Nov 2020 18:01:28

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:00:58', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'ef0bc633-863d-4281-b941-2d4fd093a13d' User entered 'No (N)'	System	06 Nov 2020 18:01:28
	System	06 Nov 2020 18:01:28

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:00:59', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'ef0bc633-863d-4281-b941-2d4fd093a13d'	System	06 Nov 2020 18:01:28
User entered 'None (1)'	System	06 Nov 2020 18:01:28

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:01:02', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'ef0bc633-863d-4281-b941-2d4fd093a13d' User entered '06 Nov 2020 12:01'	System	06 Nov 2020 18:01:28
	System	06 Nov 2020 18:01:28



US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 3'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:10:55', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd1e1404b-1397-4f9e-a161-03a70ffc74ec' User entered 'None (1)'	System	07 Nov 2020 19:11:03
	System	07 Nov 2020 19:11:03

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:19:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:10:56', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd1e1404b-1397-4f9e-a161-03a70ffc74ec' User entered 'No (N)'	System	07 Nov 2020 19:11:03
	System	07 Nov 2020 19:11:03

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:10:57', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd1e1404b-1397-4f9e-a161-03a70ffc74ec' User entered 'No (N)'	System	07 Nov 2020 19:11:03
	System	07 Nov 2020 19:11:03

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:10:58', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd1e1404b-1397-4f9e-a161-03a70ffc74ec' User entered 'None (1)'	System	07 Nov 2020 19:11:03
	System	07 Nov 2020 19:11:03

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:11:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd1e1404b-1397-4f9e-a161-03a70ffc74ec' User entered '07 Nov 2020 13:11'	System	07 Nov 2020 19:11:03
	System	07 Nov 2020 19:11:03



**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 4'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:42:43', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b74a28ab-7b1a-423e-b114-6b59e0592946'	System	08 Nov 2020 19:42:55
User entered 'None (1)'	System	08 Nov 2020 19:42:55

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:42:44', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b74a28ab-7b1a-423e-b114-6b59e0592946' User entered 'No (N)'	System	08 Nov 2020 19:42:55
	System	08 Nov 2020 19:42:55

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:42:45', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b74a28ab-7b1a-423e-b114-6b59e0592946' User entered 'No (N)'	System	08 Nov 2020 19:42:55
	System	08 Nov 2020 19:42:55

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:42:47', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b74a28ab-7b1a-423e-b114-6b59e0592946'	System	08 Nov 2020 19:42:55
User entered 'None (1)'	System	08 Nov 2020 19:42:55

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:42:50', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b74a28ab-7b1a-423e-b114-6b59e0592946' User entered '08 Nov 2020 13:42'	System	08 Nov 2020 19:42:55
	System	08 Nov 2020 19:42:55



US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '08 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:19:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '09 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 5'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:01:58', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '758eddcf-25b7-4a4f-9fea-d068c74f3233'	System	09 Nov 2020 18:02:11
User entered 'None (1)'	System	09 Nov 2020 18:02:11

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:19:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:02:02', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '758eddcf-25b7-4a4f-9fea-d068c74f3233'	System	09 Nov 2020 18:02:11
User entered 'No (N)'	System	09 Nov 2020 18:02:11

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:02:04', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '758eddcf-25b7-4a4f-9fea-d068c74f3233' User entered 'No (N)'	System	09 Nov 2020 18:02:11
	System	09 Nov 2020 18:02:11

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:02:05', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '758eddcf-25b7-4a4f-9fea-d068c74f3233'	System	09 Nov 2020 18:02:11
User entered 'None (1)'	System	09 Nov 2020 18:02:11

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:02:08', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '758eddcf-25b7-4a4f-9fea-d068c74f3233' User entered '09 Nov 2020 12:02'	System	09 Nov 2020 18:02:11
	System	09 Nov 2020 18:02:11



**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '09 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '10 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 6'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:18', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4db339f2-7728-4891-a08c-b8a92fdc40a1' User entered 'None (1)'	System	10 Nov 2020 18:08:29
	System	10 Nov 2020 18:08:29

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:19:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:20', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4db339f2-7728-4891-a08c-b8a92fdc40a1' User entered 'No (N)'	System	10 Nov 2020 18:08:29
	System	10 Nov 2020 18:08:29

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:21', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4db339f2-7728-4891-a08c-b8a92fdc40a1' User entered 'No (N)'	System	10 Nov 2020 18:08:29
	System	10 Nov 2020 18:08:29

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:22', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4db339f2-7728-4891-a08c-b8a92fdc40a1' User entered 'None (1)'	System	10 Nov 2020 18:08:29
	System	10 Nov 2020 18:08:29

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:24', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '4db339f2-7728-4891-a08c-b8a92fdc40a1' User entered '10 Nov 2020 12:08'	System	10 Nov 2020 18:08:29
	System	10 Nov 2020 18:08:29



**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '10 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '11 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 7'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:40', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'e7c150cf-89be-447b-bff7-db742c080390'	System	11 Nov 2020 18:01:52
User entered 'None (1)'	System	11 Nov 2020 18:01:52

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:19:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:42', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'e7c150cf-89be-447b-bff7-db742c080390'	System	11 Nov 2020 18:01:52
User entered 'No (N)'	System	11 Nov 2020 18:01:52

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:44', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'e7c150cf-89be-447b-bff7-db742c080390' User entered 'No (N)'	System	11 Nov 2020 18:01:52
	System	11 Nov 2020 18:01:52

US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:19:05

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:45', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'e7c150cf-89be-447b-bff7-db742c080390'	System	11 Nov 2020 18:01:52
User entered 'None (1)'	System	11 Nov 2020 18:01:52

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:47', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'e7c150cf-89be-447b-bff7-db742c080390' User entered '11 Nov 2020 12:01'	System	11 Nov 2020 18:01:52
	System	11 Nov 2020 18:01:52



US3322409

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:19:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '11 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '12 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:20:05', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '35071f45-1b8a-489a-ba4d-312b61f9253e' User entered 'None (0)'	System	05 Nov 2020 23:20:23
	System	05 Nov 2020 23:20:23

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:20:07', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '35071f45-1b8a-489a-ba4d-312b61f9253e' User entered 'None (0)'	System	05 Nov 2020 23:20:23
	System	05 Nov 2020 23:20:23

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:20:10', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '35071f45-1b8a-489a-ba4d-312b61f9253e' User entered 'None (0)'	System	05 Nov 2020 23:20:23
	System	05 Nov 2020 23:20:23

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:20:11', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '35071f45-1b8a-489a-ba4d-312b61f9253e' User entered 'None (0)'	System	05 Nov 2020 23:20:23
	System	05 Nov 2020 23:20:23

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:20:13', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '35071f45-1b8a-489a-ba4d-312b61f9253e' User entered 'None (0)'	System	05 Nov 2020 23:20:23
	System	05 Nov 2020 23:20:23



**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:20:15', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '35071f45-1b8a-489a-ba4d-312b61f9253e' User entered 'None (0)'	System	05 Nov 2020 23:20:23
	System	05 Nov 2020 23:20:23

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:20:19', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '35071f45-1b8a-489a-ba4d-312b61f9253e' User entered 'No (N)'	System	05 Nov 2020 23:20:23
	System	05 Nov 2020 23:20:23

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T17:20:21', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '35071f45-1b8a-489a-ba4d-312b61f9253e' User entered '05 Nov 2020 17:20'	System	05 Nov 2020 23:20:23
	System	05 Nov 2020 23:20:23

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Nov 2020 17:08'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Nov 2020 19:38'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 1, after vaccination (at home)'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:19:05**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:58:03', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '978a0f21-a0e9-4a20-9344-6eb37b18d66c' User entered 'None (0)'	System	06 Nov 2020 04:58:15
	System	06 Nov 2020 04:58:15

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:58:04', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '978a0f21-a0e9-4a20-9344-6eb37b18d66c' User entered 'None (0)'	System	06 Nov 2020 04:58:15
	System	06 Nov 2020 04:58:15



US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:58:05', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '978a0f21-a0e9-4a20-9344-6eb37b18d66c' User entered 'None (0)'	System	06 Nov 2020 04:58:15
	System	06 Nov 2020 04:58:15

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:58:06', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '978a0f21-a0e9-4a20-9344-6eb37b18d66c' User entered 'None (0)'	System	06 Nov 2020 04:58:15
	System	06 Nov 2020 04:58:15

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:58:07', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '978a0f21-a0e9-4a20-9344-6eb37b18d66c' User entered 'None (0)'	System	06 Nov 2020 04:58:15
	System	06 Nov 2020 04:58:15

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:58:09', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '978a0f21-a0e9-4a20-9344-6eb37b18d66c' User entered 'None (0)'	System	06 Nov 2020 04:58:15
	System	06 Nov 2020 04:58:15

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:58:10', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '978a0f21-a0e9-4a20-9344-6eb37b18d66c' User entered 'No (N)'	System	06 Nov 2020 04:58:15
	System	06 Nov 2020 04:58:15

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-05T22:58:12', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '978a0f21-a0e9-4a20-9344-6eb37b18d66c' User entered '05 Nov 2020 22:58'	System	06 Nov 2020 04:58:15
	System	06 Nov 2020 04:58:15

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '05 Nov 2020 20:33'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '06 Nov 2020 11:59'	System	05 Nov 2020 22:59:32



US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 2'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:01:04', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '29d73267-0e92-42da-8e7a-d8ce44395f9b' User entered 'None (0)'	System	06 Nov 2020 18:01:47
	System	06 Nov 2020 18:01:47

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:01:05', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '29d73267-0e92-42da-8e7a-d8ce44395f9b' User entered 'None (0)'	System	06 Nov 2020 18:01:47
	System	06 Nov 2020 18:01:47

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:01:06', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '29d73267-0e92-42da-8e7a-d8ce44395f9b' User entered 'None (0)'	System	06 Nov 2020 18:01:47
	System	06 Nov 2020 18:01:47

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:01:07', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '29d73267-0e92-42da-8e7a-d8ce44395f9b' User entered 'None (0)'	System	06 Nov 2020 18:01:47
	System	06 Nov 2020 18:01:47

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:01:08', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '29d73267-0e92-42da-8e7a-d8ce44395f9b' User entered 'None (0)'	System	06 Nov 2020 18:01:47
	System	06 Nov 2020 18:01:47

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:01:10', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '29d73267-0e92-42da-8e7a-d8ce44395f9b' User entered 'None (0)'	System	06 Nov 2020 18:01:47
	System	06 Nov 2020 18:01:47

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:01:12', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '29d73267-0e92-42da-8e7a-d8ce44395f9b' User entered 'No (N)'	System	06 Nov 2020 18:01:47
	System	06 Nov 2020 18:01:47



**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-06T12:01:14', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '29d73267-0e92-42da-8e7a-d8ce44395f9b' User entered '06 Nov 2020 12:01'	System	06 Nov 2020 18:01:47
	System	06 Nov 2020 18:01:47

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 3'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:11:02', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '32bbb112-4226-4e11-aed2-26719b73ec50' User entered 'None (0)'	System	07 Nov 2020 19:11:13
	System	07 Nov 2020 19:11:13

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:11:03', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '32bbb112-4226-4e11-aed2-26719b73ec50' User entered 'None (0)'	System	07 Nov 2020 19:11:13
	System	07 Nov 2020 19:11:13

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:11:04', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '32bbb112-4226-4e11-aed2-26719b73ec50' User entered 'None (0)'	System	07 Nov 2020 19:11:13
	System	07 Nov 2020 19:11:13

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:11:05', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '32bbb112-4226-4e11-aed2-26719b73ec50' User entered 'None (0)'	System	07 Nov 2020 19:11:13
	System	07 Nov 2020 19:11:13



US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:11:06', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '32bbb112-4226-4e11-aed2-26719b73ec50' User entered 'None (0)'	System	07 Nov 2020 19:11:13
	System	07 Nov 2020 19:11:13

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:11:07', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '32bbb112-4226-4e11-aed2-26719b73ec50' User entered 'None (0)'	System	07 Nov 2020 19:11:13
	System	07 Nov 2020 19:11:13

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:11:09', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '32bbb112-4226-4e11-aed2-26719b73ec50' User entered 'No (N)'	System	07 Nov 2020 19:11:13
	System	07 Nov 2020 19:11:13

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-07T13:11:11', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '32bbb112-4226-4e11-aed2-26719b73ec50' User entered '07 Nov 2020 13:11'	System	07 Nov 2020 19:11:13
	System	07 Nov 2020 19:11:13

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 4'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:42:52', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b5717f74-cab8-4c98-b323-6e7c6518b605' User entered 'None (0)'	System	08 Nov 2020 19:43:09
	System	08 Nov 2020 19:43:09



**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:42:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b5717f74-cab8-4c98-b323-6e7c6518b605' User entered 'None (0)'	System	08 Nov 2020 19:43:09
	System	08 Nov 2020 19:43:09

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:42:56', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b5717f74-cab8-4c98-b323-6e7c6518b605' User entered 'None (0)'	System	08 Nov 2020 19:43:09
	System	08 Nov 2020 19:43:09

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:42:57', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b5717f74-cab8-4c98-b323-6e7c6518b605' User entered 'None (0)'	System	08 Nov 2020 19:43:09
	System	08 Nov 2020 19:43:09

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:42:58', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b5717f74-cab8-4c98-b323-6e7c6518b605' User entered 'None (0)'	System	08 Nov 2020 19:43:09
	System	08 Nov 2020 19:43:09

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:43:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b5717f74-cab8-4c98-b323-6e7c6518b605' User entered 'None (0)'	System	08 Nov 2020 19:43:09
	System	08 Nov 2020 19:43:09

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:43:01', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b5717f74-cab8-4c98-b323-6e7c6518b605' User entered 'No (N)'	System	08 Nov 2020 19:43:09
	System	08 Nov 2020 19:43:09

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-08T13:43:04', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b5717f74-cab8-4c98-b323-6e7c6518b605' User entered '08 Nov 2020 13:43'	System	08 Nov 2020 19:43:09
	System	08 Nov 2020 19:43:09

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '08 Nov 2020 12:00'	System	05 Nov 2020 22:59:32



**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '09 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 5'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:02:12', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'f73ac309-d0ae-4b4a-86db-54aac2f53817' User entered 'None (0)'	System	09 Nov 2020 18:02:37
	System	09 Nov 2020 18:02:37

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:02:14', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'f73ac309-d0ae-4b4a-86db-54aac2f53817' User entered 'None (0)'	System	09 Nov 2020 18:02:37
	System	09 Nov 2020 18:02:37

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:02:16', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'f73ac309-d0ae-4b4a-86db-54aac2f53817' User entered 'None (0)'	System	09 Nov 2020 18:02:37
	System	09 Nov 2020 18:02:37

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:02:20', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'f73ac309-d0ae-4b4a-86db-54aac2f53817' User entered 'None (0)'	System	09 Nov 2020 18:02:37
	System	09 Nov 2020 18:02:37

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:02:23', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'f73ac309-d0ae-4b4a-86db-54aac2f53817' User entered 'None (0)'	System	09 Nov 2020 18:02:37
	System	09 Nov 2020 18:02:37

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:02:24', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'f73ac309-d0ae-4b4a-86db-54aac2f53817' User entered 'None (0)'	System	09 Nov 2020 18:02:37
	System	09 Nov 2020 18:02:37



US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:02:27', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'f73ac309-d0ae-4b4a-86db-54aac2f53817' User entered 'No (N)'	System	09 Nov 2020 18:02:37
	System	09 Nov 2020 18:02:37

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-09T12:02:33', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'f73ac309-d0ae-4b4a-86db-54aac2f53817' User entered '09 Nov 2020 12:02'	System	09 Nov 2020 18:02:37
	System	09 Nov 2020 18:02:37

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '09 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '10 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 6'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:27', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '2bef9092-7216-4ba0-9ed0-bc00c7b8c8a6' User entered 'None (0)'	System	10 Nov 2020 18:08:44
	System	10 Nov 2020 18:08:44

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:28', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '2bef9092-7216-4ba0-9ed0-bc00c7b8c8a6' User entered 'None (0)'	System	10 Nov 2020 18:08:44
	System	10 Nov 2020 18:08:44

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:29', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '2bef9092-7216-4ba0-9ed0-bc00c7b8c8a6' User entered 'None (0)'	System	10 Nov 2020 18:08:44
	System	10 Nov 2020 18:08:44



US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:30', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '2bef9092-7216-4ba0-9ed0-bc00c7b8c8a6' User entered 'None (0)'	System	10 Nov 2020 18:08:44
	System	10 Nov 2020 18:08:44

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:32', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '2bef9092-7216-4ba0-9ed0-bc00c7b8c8a6' User entered 'None (0)'	System	10 Nov 2020 18:08:44
	System	10 Nov 2020 18:08:44

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:34', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '2bef9092-7216-4ba0-9ed0-bc00c7b8c8a6' User entered 'None (0)'	System	10 Nov 2020 18:08:44
	System	10 Nov 2020 18:08:44

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:35', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '2bef9092-7216-4ba0-9ed0-bc00c7b8c8a6' User entered 'No (N)'	System	10 Nov 2020 18:08:44
	System	10 Nov 2020 18:08:44

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-10T12:08:37', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '2bef9092-7216-4ba0-9ed0-bc00c7b8c8a6' User entered '10 Nov 2020 12:08'	System	10 Nov 2020 18:08:44
	System	10 Nov 2020 18:08:44

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '10 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '11 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
Data entry locked.	System	05 Nov 2020 22:59:32
User entered 'Day 7'	System	05 Nov 2020 22:59:32



US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:49', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '46c5ba91-1c01-488d-ab85-2468735dc459' User entered 'None (0)'	System	11 Nov 2020 18:02:03
	System	11 Nov 2020 18:02:03

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:50', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '46c5ba91-1c01-488d-ab85-2468735dc459' User entered 'None (0)'	System	11 Nov 2020 18:02:03
	System	11 Nov 2020 18:02:03

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:51', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '46c5ba91-1c01-488d-ab85-2468735dc459' User entered 'None (0)'	System	11 Nov 2020 18:02:03
	System	11 Nov 2020 18:02:03

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:53', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '46c5ba91-1c01-488d-ab85-2468735dc459' User entered 'None (0)'	System	11 Nov 2020 18:02:03
	System	11 Nov 2020 18:02:03

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '46c5ba91-1c01-488d-ab85-2468735dc459' User entered 'None (0)'	System	11 Nov 2020 18:02:03
	System	11 Nov 2020 18:02:03

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:55', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '46c5ba91-1c01-488d-ab85-2468735dc459' User entered 'None (0)'	System	11 Nov 2020 18:02:03
	System	11 Nov 2020 18:02:03

US3322409

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:19:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:01:57', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '46c5ba91-1c01-488d-ab85-2468735dc459' User entered 'No (N)'	System	11 Nov 2020 18:02:03
	System	11 Nov 2020 18:02:03

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (87B71399-63E1-41B2-904C-84A72BDA49F1)', Time: '2020-11-11T12:02:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '46c5ba91-1c01-488d-ab85-2468735dc459' User entered '11 Nov 2020 12:02'	System	11 Nov 2020 18:02:03
	System	11 Nov 2020 18:02:03



**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '11 Nov 2020 12:00'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:19:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:36:55
User entered '12 Nov 2020 11:59'	System	05 Nov 2020 22:59:32

**US3322409**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:23:46
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 15:14:34

US3322409

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 06:12:03
User closed query 'Per source contact made on 12Nov20. Please confirm and update accordingly.' (Site from CRA).		04 Mar 2021 06:12:00
Query 'Per source contact made on 12Nov20. Please confirm and update accordingly.' answered with 'ok' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:44:38
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:44:29
User entered '12 Nov 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:44:29
User opened query 'Per source contact made on 12Nov20. Please confirm and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 21:36:51
DataPoint Verified.		25 Feb 2021 21:23:46
Query 'Per source subject was in cov. period and daily telemed visits performed and captured in symptom log. Please confirm and update accordingly' canceled (Site from CRA).		25 Feb 2021 21:23:18
User opened query 'Per source subject was in cov. period and daily telemed visits performed and captured in symptom log. Please confirm and update accordingly.' (Site from CRA).		25 Feb 2021 21:20:14
Query 'Per source contact made on 12Nov20. Please confirm with source and update accordingly.' canceled (Site from CRA).		25 Feb 2021 21:18:16
User opened query 'Per source contact made on 12Nov20. Please confirm with source and update accordingly.' (Site from CRA).		25 Feb 2021 21:17:35
User entered '13 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 15:14:34

US3322409

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:23:46
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 15:14:34

US3322409

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:23:46
User entered empty.	Elisa Moralez (b) (4)	13 Nov 2020 15:14:34

US3322409

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:20:42
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	13 Nov 2020 15:14:23

**US3322409**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'I'	System	13 Nov 2020 15:14:23



**US3322409**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:23:52
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 15:30:24

US3322409

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:23:52
User entered '19 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 15:30:24

US3322409

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:23:52
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 15:30:24

US3322409

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:23:52
User entered empty.	Elisa Moralez (b) (4)	20 Nov 2020 15:30:24

US3322409

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:23:55
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 15:30:08

**US3322409**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'I'	System	20 Nov 2020 15:30:08

**US3322409**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:32:37
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 18:53:12

US3322409

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:32:37
User entered '26 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 18:53:12



US3322409

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:32:37
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 18:53:12

US3322409

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:32:37
User entered empty.	Elisa Moralez (b) (4)	30 Nov 2020 18:53:12

US3322409

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:32:40
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 18:53:17

**US3322409**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'I'	System	30 Nov 2020 18:53:17

**US3322409**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:32:45
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Jan 2021 20:06:30

**US3322409**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:32:45
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Jan 2021 20:06:30

**US3322409**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[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 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:32:45
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Jan 2021 20:06:30

**US3322409**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'VISIT3'	System	25 Jan 2021 20:06:30



US3322409

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
DataPoint Verified.		13 Apr 2021 16:56:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	30 Dec 2020 21:28:24

**US3322409**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'I'	System	30 Dec 2020 21:28:24

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:22', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered 'Yes (Y)'	System	30 Nov 2020 20:39:18
	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:37:58', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered 'Yes (Y)'	System	30 Nov 2020 20:39:18
	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:03', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd'	System	30 Nov 2020 20:39:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:34', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered 'Yes (Y)'	System	30 Nov 2020 20:39:18
	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '0'	System	30 Nov 2020 20:39:18



**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '0'	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '0'	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '0'	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '0'	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '0'	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '0'	System	30 Nov 2020 20:39:18
	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '0'	System	30 Nov 2020 20:39:18
	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '1'	System	30 Nov 2020 20:39:18



**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '1'	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '1'	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '0'	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '0'	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '0'	System	30 Nov 2020 20:39:18
	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '0'	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '0'	System	30 Nov 2020 20:39:18
	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:54', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '0'	System	30 Nov 2020 20:39:18



**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:38:57', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd'	System	30 Nov 2020 20:39:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:39:01', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered 'No (N)'	System	30 Nov 2020 20:39:18
	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-11-30T14:39:05', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'b1914955-5ada-4f8d-83a5-6a4112e4f8bd' User entered '30 Nov 2020 14:39:05'	System	30 Nov 2020 20:39:18
	System	30 Nov 2020 20:39:18

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-12-06T00:03:20', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd67e6294-ed83-4dc1-b532-3289d40444f1'	System	06 Dec 2020 06:03:45
User entered 'No (N)'	System	06 Dec 2020 06:03:45

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-12-06T00:03:31', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd67e6294-ed83-4dc1-b532-3289d40444f1'	System	06 Dec 2020 06:03:45
User entered 'Yes (Y)'	System	06 Dec 2020 06:03:45



**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-12-06T00:03:33', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd67e6294-ed83-4dc1-b532-3289d40444f1'	System	06 Dec 2020 06:03:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Dec 2020 06:03:45

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-12-06T00:03:35', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd67e6294-ed83-4dc1-b532-3289d40444f1' User entered '06 Dec 2020 00:03:35'	System	06 Dec 2020 06:03:45
	System	06 Dec 2020 06:03:45

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-12-13T01:43:35', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'a8a4fd81-1141-4f91-adae-f15607756af8' User entered 'No (N)'	System	13 Dec 2020 07:43:48
	System	13 Dec 2020 07:43:48

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-12-13T01:43:44', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'a8a4fd81-1141-4f91-adae-f15607756af8' User entered 'No (N)'	System	13 Dec 2020 07:43:48

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-12-13T01:43:46', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'a8a4fd81-1141-4f91-adae-f15607756af8' User entered '13 Dec 2020 01:43:46'	System	13 Dec 2020 07:43:48
	System	13 Dec 2020 07:43:48



**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-12-21T15:33:48', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '00aa1997-bb0c-4a76-9983-f292c2d569fe' User entered 'No (N)'	System	21 Dec 2020 21:33:58
	System	21 Dec 2020 21:33:58

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-12-21T15:33:52', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '00aa1997-bb0c-4a76-9983-f292c2d569fe' User entered 'No (N)'	System	21 Dec 2020 21:33:58
	System	21 Dec 2020 21:33:58

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-12-21T15:33:55', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '00aa1997-bb0c-4a76-9983-f292c2d569fe' User entered '21 Dec 2020 15:33:55'	System	21 Dec 2020 21:33:58
	System	21 Dec 2020 21:33:58

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 11:36:12



**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-12-27T09:11:28', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '7abdfc19-aaf8-4d2f-8d97-03736100c617'	System	27 Dec 2020 15:11:45
User entered 'No (N)'	System	27 Dec 2020 15:11:45

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-12-27T09:11:40', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '7abdfc19-aaf8-4d2f-8d97-03736100c617'	System	27 Dec 2020 15:11:45
User entered 'No (N)'	System	27 Dec 2020 15:11:45

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2020-12-27T09:11:43', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '7abdf19-aaf8-4d2f-8d97-03736100c617' User entered '27 Dec 2020 09:11:43'	System	27 Dec 2020 15:11:45
	System	27 Dec 2020 15:11:45

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-03T00:52:30', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '955ac23e-a1e2-4739-a7d5-3f950ad7b584' User entered 'No (N)'	System	03 Jan 2021 06:52:55
	System	03 Jan 2021 06:52:55



**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-03T00:52:41', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '955ac23e-a1e2-4739-a7d5-3f950ad7b584' User entered 'Yes (Y)'	System	03 Jan 2021 06:52:55
	System	03 Jan 2021 06:52:55

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-03T00:52:44', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '955ac23e-a1e2-4739-a7d5-3f950ad7b584'	System	03 Jan 2021 06:52:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Jan 2021 06:52:55

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-03T00:52:46', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '955ac23e-a1e2-4739-a7d5-3f950ad7b584' User entered '03 Jan 2021 00:52:46'	System	03 Jan 2021 06:52:55
	System	03 Jan 2021 06:52:55

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-10T00:01:12', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5d974db3-9dd1-4cd4-9304-0e41d6906b81'	System	10 Jan 2021 06:01:39
User entered 'No (N)'	System	10 Jan 2021 06:01:39

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-10T00:01:23', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5d974db3-9dd1-4cd4-9304-0e41d6906b81'	System	10 Jan 2021 06:01:39
User entered 'Yes (Y)'	System	10 Jan 2021 06:01:39



**US3322409**

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

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**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-10T00:01:25', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5d974db3-9dd1-4cd4-9304-0e41d6906b81'	System	10 Jan 2021 06:01:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 06:01:39

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-10T00:01:28', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5d974db3-9dd1-4cd4-9304-0e41d6906b81' User entered '10 Jan 2021 00:01:28'	System	10 Jan 2021 06:01:39

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-17T00:07:52', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'e555c252-fd9e-4592-b4f5-4640586dad27'	System	17 Jan 2021 06:08:10
User entered 'No (N)'	System	17 Jan 2021 06:08:10

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-17T00:07:55', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'e555c252-fd9e-4592-b4f5-4640586dad27'	System	17 Jan 2021 06:08:10
User entered 'Yes (Y)'	System	17 Jan 2021 06:08:10

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-17T00:07:57', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'e555c252-fd9e-4592-b4f5-4640586dad27'	System	17 Jan 2021 06:08:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Jan 2021 06:08:10



**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-17T00:08:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'e555c252-fd9e-4592-b4f5-4640586dad27' User entered '17 Jan 2021 00:08:00'	System	17 Jan 2021 06:08:10
	System	17 Jan 2021 06:08:10

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-24T00:01:18', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '55f9ce06-7be9-4eba-b769-fc127187ab02'	System	24 Jan 2021 06:02:44
User entered 'No (N)'	System	24 Jan 2021 06:02:44

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-24T00:01:22', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '55f9ce06-7be9-4eba-b769-fc127187ab02'	System	24 Jan 2021 06:02:44
User entered 'Yes (Y)'	System	24 Jan 2021 06:02:44

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-24T00:02:16', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '55f9ce06-7be9-4eba-b769-fc127187ab02'	System	24 Jan 2021 06:02:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	24 Jan 2021 06:02:44

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-01-24T00:02:18', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '55f9ce06-7be9-4eba-b769-fc127187ab02'	System	24 Jan 2021 06:02:44
User entered '24 Jan 2021 00:02:18'	System	24 Jan 2021 06:02:44



**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:36:12

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-02T07:03:49', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'a5d354b6-5913-4f4e-a476-3675bf790a9e' User entered 'No (N)'	System	03 Feb 2021 15:55:44
	System	03 Feb 2021 15:55:44

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-02T07:03:51', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'a5d354b6-5913-4f4e-a476-3675bf790a9e' User entered 'Yes (Y)'	System	03 Feb 2021 15:55:44
	System	03 Feb 2021 15:55:44

**US3322409**

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

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**Generated On: 11 Aug 2021 22:19:05**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-02T07:03:53', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'a5d354b6-5913-4f4e-a476-3675bf790a9e'	System	03 Feb 2021 15:55:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	03 Feb 2021 15:55:44

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-02T07:03:56', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'a5d354b6-5913-4f4e-a476-3675bf790a9e' User entered '02 Feb 2021 07:03:56'	System	03 Feb 2021 15:55:44
	System	03 Feb 2021 15:55:44

**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 11:36:12



**US3322409**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-07T00:21:32', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '46b8eefd-fd15-434c-b375-57d8e8c53acf' User entered 'No (N)'	System	07 Feb 2021 06:22:17
	System	07 Feb 2021 06:22:17

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-07T00:21:36', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '46b8eefd-fd15-434c-b375-57d8e8c53acf'	System	07 Feb 2021 06:22:17
User entered 'Yes (Y)'	System	07 Feb 2021 06:22:17

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-07T00:21:38', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '46b8eefd-fd15-434c-b375-57d8e8c53acf'	System	07 Feb 2021 06:22:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Feb 2021 06:22:17

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-07T00:21:57', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '46b8eefd-fd15-434c-b375-57d8e8c53acf' User entered '07 Feb 2021 00:21:57'	System	07 Feb 2021 06:22:17
	System	07 Feb 2021 06:22:17

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-14T00:01:27', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0f02725a-ac28-4e05-b881-18c7c10af2ba' User entered 'No (N)'	System	14 Feb 2021 06:01:56
	System	14 Feb 2021 06:01:56

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-14T00:01:35', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0f02725a-ac28-4e05-b881-18c7c10af2ba'	System	14 Feb 2021 06:01:56
User entered 'No (N)'	System	14 Feb 2021 06:01:56

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-14T00:01:37', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0f02725a-ac28-4e05-b881-18c7c10af2ba' User entered '14 Feb 2021 00:01:37'	System	14 Feb 2021 06:01:56
	System	14 Feb 2021 06:01:56

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-21T00:01:17', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '8aef3551-bdcc-4bb2-b82c-8c22404211e7' User entered 'Yes (Y)'	System	21 Feb 2021 06:02:16
	System	21 Feb 2021 06:02:16



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-21T00:01:22', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '8aef3551-bdcc-4bb2-b82c-8c22404211e7' User entered 'No (N)'	System	21 Feb 2021 06:02:16

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-21T00:01:29', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '8aef3551-bdcc-4bb2-b82c-8c22404211e7' User entered 'No (N)'	System	21 Feb 2021 06:02:16
	System	21 Feb 2021 06:02:16

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-21T00:01:37', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '8aef3551-bdcc-4bb2-b82c-8c22404211e7' User entered 'No (N)'	System	21 Feb 2021 06:02:16
	System	21 Feb 2021 06:02:16

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-21T00:01:41', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '8aef3551-bdcc-4bb2-b82c-8c22404211e7' User entered '21 Feb 2021 00:01:41'	System	21 Feb 2021 06:02:16
	System	21 Feb 2021 06:02:16

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-28T00:51:04-06:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5c7f48a9-bb76-443a-bdbf-0a7346ec9b9b'	System	28 Feb 2021 06:51:23
User entered 'No (N)'	System	28 Feb 2021 06:51:23



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-28T00:51:11-06:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5c7f48a9-bb76-443a-bdbf-0a7346ec9b9b'	System	28 Feb 2021 06:51:23
User entered 'Yes (Y)'	System	28 Feb 2021 06:51:23

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-28T00:51:12-06:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5c7f48a9-bb76-443a-bdbf-0a7346ec9b9b'	System	28 Feb 2021 06:51:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	28 Feb 2021 06:51:23

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-28T00:51:14-06:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '5c7f48a9-bb76-443a-bdbf-0a7346ec9b9b' User entered '28 Feb 2021 06:51:14'	System	28 Feb 2021 06:51:23
	System	28 Feb 2021 06:51:23

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-03-07T00:25:06-06:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0177d675-e122-4625-9eb2-2d82f9139082'	System	07 Mar 2021 06:25:14
User entered 'No (N)'	System	07 Mar 2021 06:25:14

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-03-07T00:25:08-06:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0177d675-e122-4625-9eb2-2d82f9139082'	System	07 Mar 2021 06:25:14
User entered 'No (N)'	System	07 Mar 2021 06:25:14



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-03-07T00:25:11-06:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '0177d675-e122-4625-9eb2-2d82f9139082'	System	07 Mar 2021 06:25:14
User entered '07 Mar 2021 00:25:11'	System	07 Mar 2021 06:25:14

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-03-15T11:27:18-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'fc0557e9-f446-4d31-896e-43e00f60b3e5'	System	15 Mar 2021 16:27:25
User entered 'No (N)'	System	15 Mar 2021 16:27:25

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-03-15T11:27:20-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'fc0557e9-f446-4d31-896e-43e00f60b3e5'	System	15 Mar 2021 16:27:25
User entered 'No (N)'	System	15 Mar 2021 16:27:25

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-03-15T11:27:22-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'fc0557e9-f446-4d31-896e-43e00f60b3e5' User entered '15 Mar 2021 11:27:22'	System	15 Mar 2021 16:27:25
	System	15 Mar 2021 16:27:25

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-03-21T00:08:35-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '225875e7-2d4e-4520-b687-fd5929671979'	System	21 Mar 2021 05:08:45
User entered 'No (N)'	System	21 Mar 2021 05:08:45

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-03-21T00:08:37-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '225875e7-2d4e-4520-b687-fd5929671979'	System	21 Mar 2021 05:08:45
User entered 'No (N)'	System	21 Mar 2021 05:08:45

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-03-21T00:08:40-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '225875e7-2d4e-4520-b687-fd5929671979'	System	21 Mar 2021 05:08:45
User entered '21 Mar 2021 00:08:40'	System	21 Mar 2021 05:08:45

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-03-28T00:02:14-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '7ea0a460-c4e5-41f9-9601-b7ab38355a2b'	System	28 Mar 2021 05:02:23
User entered 'No (N)'	System	28 Mar 2021 05:02:23

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-03-28T00:02:16-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '7ea0a460-c4e5-41f9-9601-b7ab38355a2b'	System	28 Mar 2021 05:02:23
User entered 'No (N)'	System	28 Mar 2021 05:02:23

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-03-28T00:02:18-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '7ea0a460-c4e5-41f9-9601-b7ab38355a2b' User entered '28 Mar 2021 00:02:18'	System	28 Mar 2021 05:02:23
	System	28 Mar 2021 05:02:23

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-04-04T00:02:11-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd98e579d-be2f-416b-8f40-a738cddc03bf'	System	04 Apr 2021 05:02:19
User entered 'No (N)'	System	04 Apr 2021 05:02:19

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-04-04T00:02:13-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd98e579d-be2f-416b-8f40-a738cddc03bf'	System	04 Apr 2021 05:02:19
User entered 'No (N)'	System	04 Apr 2021 05:02:19



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-04-04T00:02:15-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd98e579d-be2f-416b-8f40-a738cddc03bf'	System	04 Apr 2021 05:02:19
User entered '04 Apr 2021 00:02:15'	System	04 Apr 2021 05:02:19

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-04-11T00:39:15-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '473fa5d4-2b8b-4f4e-af86-bf31a23f5c9b'	System	11 Apr 2021 05:39:21
User entered 'No (N)'	System	11 Apr 2021 05:39:21

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-04-11T00:39:17-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '473fa5d4-2b8b-4f4e-af86-bf31a23f5c9b'	System	11 Apr 2021 05:39:21
User entered 'No (N)'	System	11 Apr 2021 05:39:21

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-04-11T00:39:19-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '473fa5d4-2b8b-4f4e-af86-bf31a23f5c9b'	System	11 Apr 2021 05:39:21
User entered '11 Apr 2021 00:39:19'	System	11 Apr 2021 05:39:21

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 11:36:12



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-04-19T10:47:57-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '03c1588d-81bb-4d1e-9fdd-105ea12efe50'	System	19 Apr 2021 15:48:08
User entered 'No (N)'	System	19 Apr 2021 15:48:08

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-04-19T10:47:59-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '03c1588d-81bb-4d1e-9fdd-105ea12efe50'	System	19 Apr 2021 15:48:08
User entered 'No (N)'	System	19 Apr 2021 15:48:08

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-04-19T10:48:01-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '03c1588d-81bb-4d1e-9fdd-105ea12efe50'	System	19 Apr 2021 15:48:08
User entered '19 Apr 2021 10:48:01'	System	19 Apr 2021 15:48:08

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-04-25T08:39:56-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '2e142cd5-d2f4-4a95-a49b-5c4f54b25091'	System	25 Apr 2021 13:40:13
User entered 'No (N)'	System	25 Apr 2021 13:40:13

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-04-25T08:40:05-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '2e142cd5-d2f4-4a95-a49b-5c4f54b25091' User entered 'No (N)'	System	25 Apr 2021 13:40:13
	System	25 Apr 2021 13:40:13

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-04-25T08:40:07-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: '2e142cd5-d2f4-4a95-a49b-5c4f54b25091'	System	25 Apr 2021 13:40:13
User entered '25 Apr 2021 08:40:07'	System	25 Apr 2021 13:40:13

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-05-02T00:16:25-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd8f72b2a-f630-4257-b988-46325ec2c180'	System	02 May 2021 05:16:32
User entered 'No (N)'	System	02 May 2021 05:16:32

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

Have you been exposed to someone with 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 (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-05-02T00:16:26-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd8f72b2a-f630-4257-b988-46325ec2c180'	System	02 May 2021 05:16:32
User entered 'No (N)'	System	02 May 2021 05:16:32



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-05-02T00:16:28-05:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'd8f72b2a-f630-4257-b988-46325ec2c180'	System	02 May 2021 05:16:32
User entered '02 May 2021 00:16:28'	System	02 May 2021 05:16:32

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:36:12

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 11:36:12

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 11:36:12

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:36:12

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 11:36:12



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 11:36:12

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 11:36:12



**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 11:36:12

**US3322409**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:19:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:36:12
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 11:36:12

US3322409

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:19:05**

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 19:43:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-27T17:47:16-06:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'f6b78995-01d9-4b4d-99ce-70a1507c7c22'	System	27 Feb 2021 23:47:25
User entered 'No (N)'	System	27 Feb 2021 23:47:25

**US3322409**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:43:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (AC28DC16-D73B-4B0E-9B63-84AE33453EA7)', Time: '2021-02-27T17:47:22-06:00', User OID: 'PatientReportedOutcome (US3322409)', ODM File OID: 'f6b78995-01d9-4b4d-99ce-70a1507c7c22'	System	27 Feb 2021 23:47:25
User entered '27 Feb 2021 23:47:22'	System	27 Feb 2021 23:47:25

**US3322409**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:34:20
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	30 Dec 2020 21:28:33

**US3322409**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:34:20
User entered '29 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	30 Dec 2020 21:28:33



US3322409

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:34:20
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	30 Dec 2020 21:28:33

US3322409

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 21:34:20
User entered empty.	Elisa Moralez (b) (4)	30 Dec 2020 21:28:33

US3322409

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:34:24
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	30 Dec 2020 21:28:36

**US3322409**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:46:20
User entered 'I'	System	30 Dec 2020 21:28:36

**US3322409**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 06:11:11
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:05:56

US3322409

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 06:11:11
User closed query 'Per source contact made 01Feb21. Please confirm with source and update.' (Site from CRA).		04 Mar 2021 06:11:08
Query 'Per source contact made 01Feb21. Please confirm with source and update.' answered with 'ok' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:44:15
User entered '01 Feb 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:44:05
User opened query 'Per source contact made 01Feb21. Please confirm with source and update.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 21:35:40
User entered '02 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:05:56

**US3322409**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 06:11:11
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:05:56

US3322409

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 06:11:11
User entered empty.	Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:05:56



US3322409

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:35:47
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 22:05:41

**US3322409**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:18:45
User entered 'I'	System	03 Feb 2021 22:05:41

**US3322409**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:18:45
DataPoint Verified.		13 Apr 2021 16:57:01
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 20:08:38

US3322409

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:18:45
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 00:46:56
User closed query 'Per source, visit was completed and contact made on 02Mar2021. Please confirm where the 03Mar2021 date came from and whether EDC should be updated or not. ' (Site from CRA). Query 'Per source, visit was completed and contact made on 02Mar2021. Please confirm where the 03Mar2021 date came from and whether EDC should be updated or not. ' answered with 'data entry error, confirmed correct date 02mar2021 with source, thank you' (Site from CRA).		14 Apr 2021 00:46:43
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	13 Apr 2021 17:16:27
User entered '02 Mar 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	13 Apr 2021 17:16:06
User opened query 'Per source, visit was completed and contact made on 02Mar2021. Please confirm where the 03Mar2021 date came from and whether EDC should be updated or not. ' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 16:59:57
DataPoint Verified.		13 Apr 2021 16:59:20
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	13 Apr 2021 16:57:01
User entered '03 Mar 2021'	Elisa Moralez (b) (4) (b) (4)	24 Mar 2021 22:12:52
		10 Mar 2021 20:08:38

US3322409

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:18:45
DataPoint Verified.		13 Apr 2021 16:57:01
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 20:08:38

US3322409

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:18:45
DataPoint Verified.		13 Apr 2021 16:57:01
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 20:08:38

US3322409

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:18:45
DataPoint Verified.		13 Apr 2021 16:57:28
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	10 Mar 2021 20:08:41

**US3322409**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:18:45
User entered 'I'	System	10 Mar 2021 20:08:41



**US3322409**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:01:54
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 15:34:08

US3322409

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:01:54
User entered '01 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 15:34:08

US3322409

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:01:54
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 15:34:17
User entered 'Contact Not Made (CONTACT NOT MADE)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 15:34:08

US3322409

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:01:54
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	06 Apr 2021 15:34:17
Please review and reconcile.' (Site from System).		
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	06 Apr 2021 15:34:08
Please review and reconcile.' (Site from System).		
User entered empty.	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 15:34:08

US3322409

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:02:11
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	06 Apr 2021 15:34:12

**US3322409**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	06 Apr 2021 15:34:12

**US3322409**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 14:35:07
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	19 Apr 2021 17:43:57
	(b) (4)	

US3322409

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:19:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 17:24:19 20 Apr 2021 14:35:07
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'per source, date is accurate' (Site from System).	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:44:14
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	19 Apr 2021 17:43:57
User entered '19 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:43:57



US3322409

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:19:05

[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 16:39:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 14:35:07
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	19 Apr 2021 17:43:57
	(b) (4)	

**US3322409**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	19 Apr 2021 17:43:57

US3322409

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:35:23
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:44:46

US3322409

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:35:23
User entered '19 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:44:46

US3322409

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 14:35:23
User entered '11:46'	Elisa Moralez (b) (4)	19 Apr 2021 17:44:46
	(b) (4)	

**US3322409**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Apr 2021 11:46'	System	19 Apr 2021 17:44:46

US3322409

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 14:35:23
User entered '97.7' F	Elisa Moralez (b) (4)	19 Apr 2021 17:44:46
	(b) (4)	

US3322409

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:35:23
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:44:46



**US3322409**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:35:23
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:44:46

US3322409

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:35:23
User entered '80'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:44:46

**US3322409**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Apr 2021 17:44:46

US3322409

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 14:35:23
User entered '16'	Elisa Moralez (b) (4)	19 Apr 2021 17:44:46
	(b) (4)	

**US3322409**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Apr 2021 17:44:46

US3322409

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:35:23
User entered '107'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:44:46

**US3322409**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 17:44:46

US3322409

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:35:23
User entered '69'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:44:46



US3322409

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 17:44:46

US3322409

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:35:31
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:44:54

US3322409

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:35:31
User entered empty.	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:44:54

**US3322409**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:19:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:35:39
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:45:03

US3322409

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:19:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:35:39
User entered '19 Apr 2021'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:45:03

**US3322409**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:19:05**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:35:39
User entered '12:03'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:45:03

**US3322409**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Apr 2021 12:03'	System	19 Apr 2021 17:45:03

US3322409

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:39:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:35:43
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	19 Apr 2021 17:45:06



**US3322409**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 17:45:06

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:19:05

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:46:17
User entered '13 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:39:45

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:19:05

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:46:17
User entered '8:57'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:39:45

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:19:05

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:24
User entered '13 Nov 2020 8:57'	System	16 Nov 2020 15:39:45

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:19:05

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:46:17
User entered 'Safety Call (Safety Call)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:39:45

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:19:05

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 15:46:17
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:39:45

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 1 (Day 1)'	Elisa Moralez (b) (4)	16 Nov 2020 15:46:13

**US3322409**

**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: Symptom Log (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered '7 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User closed query 'Per CDM: It appears that Assessment Not Done is checked yet data is present for Day 1 TO Day 6. Please reconcile and update accordingly.' (Site from DM).		15 Jan 2021 09:51:08
Query 'Per CDM: It appears that Assessment Not Done is checked yet data is present for Day 1 TO Day 6. Please reconcile and update accordingly.' answered with 'done' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	08 Jan 2021 15:25:38
User entered '0' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Jan 2021 15:25:22
User opened query 'Per CDM: It appears that Assessment Not Done is checked yet data is present for Day 1 TO Day 6. Please reconcile and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 07:41:19
Query 'Per CDM: It appears that Assessment Not Done is checked yet data is present for Day 1 TO Day 6. Please reconcile and update accordingly' 'canceled (Site from DM).		08 Jan 2021 07:41:11
User opened query 'Per CDM: It appears that Assessment Not Done is checked yet data is present for Day 1 TO Day 6. Please reconcile and update accordingly' (Site from DM).		08 Jan 2021 07:41:03
User entered '1'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered missing code ND - Not Done; reason for change Data Entry Error	Elisa Moralez (b) (4)	08 Jan 2021 15:25:22
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	08 Jan 2021 15:25:22
User entered empty.	System	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Jan 2021 15:25:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Jan 2021 15:25:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Jan 2021 15:25:22
User entered 'd' (non-conformant).	Elisa Moralez (b) (4) (b) (4)	08 Jan 2021 15:25:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:49
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 2 (Day 2)'	Elisa Moralez (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered '8 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered '0' reason for change: Data Entry Error	Elisa Moralez (b) (4)	08 Jan 2021 15:25:22
User entered '1'	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered missing code ND - Not Done; reason for change Data Entry Error	Elisa Moralez (b) (4)	08 Jan 2021 15:25:22
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	08 Jan 2021 15:25:22
User entered empty.	System	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Jan 2021 15:25:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Jan 2021 15:25:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Jan 2021 15:25:22
User entered 'd' (non-conformant).	Elisa Moralez (b) (4) (b) (4)	08 Jan 2021 15:25:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 3 (Day 3)'	Elisa Moralez (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered '9 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered '0' reason for change: Data Entry Error	Elisa Moralez (b) (4)	08 Jan 2021 15:25:22
User entered '1'	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Elisa Moralez (b) (4)	08 Jan 2021 15:25:22
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	08 Jan 2021 15:25:22
User entered empty.	System	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Elisa Moralez (b) (4)	08 Jan 2021 15:25:22
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

**US3322409**

**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: Symptom Log (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 4 (Day 4)'	Elisa Moralez (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered '10 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered '0' reason for change: Data Entry Error	Elisa Moralez (b) (4)	08 Jan 2021 15:25:22
User entered '1'	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Elisa Moralez (b) (4)	08 Jan 2021 15:25:22
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	08 Jan 2021 15:25:22
User entered empty.	System	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Jan 2021 15:25:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 5 (Day 5)'	Elisa Moralez (b) (4)	16 Nov 2020 15:46:13

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**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered '11 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered '0' reason for change: Data Entry Error	Elisa Moralez (b) (4)	08 Jan 2021 15:25:22
User entered '1'	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Elisa Moralez (b) (4)	08 Jan 2021 15:25:22
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	08 Jan 2021 15:25:22
User entered empty.	System	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered missing code ND - Not Done; reason for change Data Entry Error	Elisa Moralez (b) (4)	08 Jan 2021 15:25:22
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

**US3322409**

**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: Symptom Log (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 6 (Day 6)'	Elisa Moralez (b) (4)	16 Nov 2020 15:46:13

**US3322409**

**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: Symptom Log (6)**

**Generated On: 11 Aug 2021 22:19:05**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered '12 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered '0' reason for change: Data Entry Error	Elisa Moralez (b) (4)	08 Jan 2021 15:25:22
User entered '1'	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Elisa Moralez (b) (4)	08 Jan 2021 15:25:22
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	08 Jan 2021 15:25:22
User entered empty.	System	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered missing code ND - Not Done; reason for change Data Entry Error	Elisa Moralez (b) (4)	08 Jan 2021 15:25:22
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:42:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 7 (Day 7)'	Elisa Moralez (b) (4)	16 Nov 2020 15:46:13

**US3322409**

**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: Symptom Log (7)**

**Generated On: 11 Aug 2021 22:19:05**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered '13 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered '99.1' F	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:43:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 8 (Day 8)'	Elisa Moralez (b) (4)	16 Nov 2020 15:46:13

**US3322409**

**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: Symptom Log (8)**

**Generated On: 11 Aug 2021 22:19:05**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:34:57
User entered '14 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:02
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:00
User closed query 'Per source, it states that the O2 saturation as 98. Please confirm and update accordingly.' (Site from CRA).		20 Nov 2020 17:34:47
Query 'Per source, it states that the O2 saturation as 98. Please confirm and update accordingly.' answered with 'updated' (Site from CRA).	Blessing Felix-Okoroji (b) (4)	20 Nov 2020 17:13:25
User entered '98' reason for change: Per Query Resolution	Blessing Felix-Okoroji (b) (4)	20 Nov 2020 17:13:16
User opened query 'Per source, it states that the O2 saturation as 98. Please confirm and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 16:51:21
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	20 Nov 2020 17:13:16
User entered empty.	System	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:44:08
User closed query 'Per source, it states that the temperature was 98.7. Please confirm and update accordingly.' (Site from CRA).		20 Nov 2020 17:34:51
Query 'Per source, it states that the temperature was 98.7. Please confirm and update accordingly.' answered with 'updated' (Site from CRA).	Blessing Felix-Okoroji (b) (4)	20 Nov 2020 17:13:31
User entered '98.7' F reason for change: Per Query Resolution	Blessing Felix-Okoroji (b) (4)	20 Nov 2020 17:13:16
User opened query 'Per source, it states that the temperature was 98.7. Please confirm and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 16:52:14
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:06
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:08
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:09
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:13
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:15
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:18
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:19
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:24
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:26
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:28
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:32
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:30
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:33
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:35:34
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 9 (Day 9)'	Elisa Moralez (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered '15 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:32:46
User closed query 'Per source, it states that the O2 Saturation is 98. Please confirm and update accordingly' (Site from CRA).		19 Feb 2021 19:32:40
Query 'Per source, it states that the O2 Saturation is 98. Please confirm and update accordingly' answered with 'thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:19:44
User entered '98' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:19:38
User opened query 'Per source, it states that the O2 Saturation is 98. Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 18:13:16
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	23 Nov 2020 15:19:38
User entered empty.	System	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:32:54
User closed query 'Per source, it states that the temperature was 98.3. Please confirm and update accordingly.' (Site from CRA).		20 Nov 2020 18:10:54
Query 'Per source, it states that the temperature was 98.3. Please confirm and update accordingly.' answered with 'updated' (Site from CRA).	Blessing Felix-Okoroji (b) (4)	20 Nov 2020 17:14:47
User entered '98.3' F reason for change: Per Query Resolution	Blessing Felix-Okoroji (b) (4)	20 Nov 2020 17:14:40
User opened query 'Per source, it states that the temperature was 98.3. Please confirm and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 16:55:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:34
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:45:50
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:13

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 10 (Day 10)'	Elisa Moralez (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:57
User entered '16 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:55
User entered '0'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:51
User entered '98'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:49
User entered '99.1' F	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:47:08
DataPoint Un-verified.		20 Nov 2020 17:08:59
DataPoint Verified.		20 Nov 2020 17:08:47
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:40
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:39
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:37
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:35
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:33
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:31
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:22
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:19
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:14
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:08:13
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 14:44:12

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 11 (Day 11)'	Frances Saubon (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:24:02
User entered '17 Nov 2020'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:24:00
User entered '0'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:48
User entered '97'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

**US3322409**

**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: Symptom Log (11)**

**Generated On: 11 Aug 2021 22:19:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:44
User entered '98.3' F	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:38
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:37
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:35
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:34
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:29
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:27
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:25
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:23
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:21
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:19
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:14
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:13
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:11
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:07
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:10
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:23:05
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 19:59:42



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 12 (Day 12)'	Frances Saubon (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:25:26
User entered '18 Nov 2020'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:25:31
User entered '0'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:25:33
User entered '99'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

**US3322409**

**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: Symptom Log (12)**

**Generated On: 11 Aug 2021 22:19:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:25:54
User entered '96.9' F	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:04
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:07
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:11
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:13
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:15
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:20
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:22
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:26
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:31
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:33
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:35
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:37
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:41
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:43
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:45
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:26:47
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 20:01:27

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 13 (Day 13)'	Elisa Moralez (b) (4)	20 Nov 2020 17:24:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:04
User entered '19 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:10
User entered '0'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:13
User entered '99'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

**US3322409**

**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: Symptom Log (13)**

**Generated On: 11 Aug 2021 22:19:05**

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	20 Nov 2020 17:24:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:19
User entered '98.4' F	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:21
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:23
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:25
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:27
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:29
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:31
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:36
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:38
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:40
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:42
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:44
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:46
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:48
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:52
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:54
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:28:56
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:24:40

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 14 (Day 14)'	Elisa Moralez (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered '20 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered '97'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered '98.1' F	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:17
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 15 (Day 15)'	Elisa Moralez (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered '21 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered '100'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered '97.6' F	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

**US3322409**

**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: Symptom Log (15)**

**Generated On: 11 Aug 2021 22:19:05**

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:49:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 16 (Day 16)'	Elisa Moralez (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered '22 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered '100'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered '98.8' F	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:01
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:18:34

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 17 (Day 17)'	Elisa Moralez (b) (4)	24 Nov 2020 15:28:38

**US3322409**

**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: Symptom Log (17)**

**Generated On: 11 Aug 2021 22:19:05**

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered '23 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered '0'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered '97'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered '98.2' F	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:53:00
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	24 Nov 2020 15:28:38

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 18 (Day 18)'	Elisa Moralez (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered '24 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered '98'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered '97.5' F	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:58
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 19 (Day 19)'	Elisa Moralez (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered '25 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered '100'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered '99.1' F	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:57
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'Day 20 (Day 20)'	Elisa Moralez (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered '26 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered '97'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User entered '%'	System	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered '98.9' F	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:19:05

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 21:52:55
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 17:57:53

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:19:05

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:15:59
User entered '13 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:26

**US3322409**

**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:19:05**

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:15:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:26



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:19:05

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:15:59
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).		19 Nov 2020 21:25:50
User closed query 'Data is required. Please complete.' (Site from System).		19 Nov 2020 21:25:45
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'ok' (Site from System).	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:10
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	17 Nov 2020 17:04:01
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:01
Query 'Data is required. Please complete.' answered with 'results are still pending' (Site from System).	Frances Saubon (b) (4) (b) (4)	16 Nov 2020 16:06:12
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Nov 2020 15:46:26
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:26

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:19:05

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:15:59
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 13-NOV-2020 is recorded under Covid-19 Assessment in EDC; however, the swab sample for 13-NOV-2020 is reported under "Illness Visit Day 1" in PPD portal. Please reconcile the correct visit and update if applicable, else clarify the correct visit in site response.		18 Nov 2020 06:24:29
' canceled (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 13-NOV-2020 is recorded under Covid-19 Assessment in EDC; however, the swab sample for 13-NOV-2020 is reported under "Illness Visit Day 1" in PPD portal. Please reconcile the correct visit and update if applicable, else clarify the correct visit in site response.	(b) (4), (b) (6)	18 Nov 2020 06:22:04
' (Site from DM).		
User entered '13 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:26

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:19:05

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:15:59
User entered 'Nasal Swab (Nasal Swab)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:26

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:19:05

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:15:59
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:26

**US3322409**

**Folder: Covid-19 Assessment 13 Nov 2020**

**Form: COVID Diagnostic Test**

**Generated On: 11 Aug 2021 22:19:05**

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:15:59
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:26

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:19:05

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:15:59
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:26

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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:19:05

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:45
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:15:59
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:46:26

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:19:05

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:45
User entered 'I'	System	17 Nov 2020 17:04:01



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

Did the subject have Respiratory Rates  $\geq 30$  per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

Did the subject have Heart Rate  $\geq$  125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

Did the subject have Oxygen Saturation of SpO2  $\leq$  93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39



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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

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Generated On: 11 Aug 2021 22:19:05

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 17:04:47
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 17:04:47
User entered 'No (N)' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:47
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 17:04:39
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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[Start Date](#)

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39



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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

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[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

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Generated On: 11 Aug 2021 22:19:05

[Evidence of Shock Requires  
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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[Start Date](#)

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

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Folder: Covid-19 Assessment 13 Nov 2020

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39



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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39



US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:19:05

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:45:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:37:49
User entered empty.	Elisa Moralez (b) (4) (b) (4)	17 Nov 2020 17:04:39

US3322409

Folder: Covid-19 Assessment 13 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:19:05

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:46:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:37:51
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 21:51:20

US3322409

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:19:05

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User closed query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).		18 Jan 2021 04:46:08
Query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' answered with 'only information available in source is number 1F605059282 date shipped 16-nov-2020' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 17:02:42
User opened query 'Per GCL Lab Reconciliation: Saliva: Per previous query response, since the sample is shipped. Please confirm the Accession number and tracking number with shipping date in the response for the tracking the sample in PPD as the sample is still missing in PPD.' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 10:41:36
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,17,19,20NOV2020 is recorded under Illness Visit Day 3,5,7,9in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		14 Dec 2020 09:14:30
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,17,19,20NOV2020 is recorded under Illness Visit Day 3,5,7,9in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'Accession number now being updated in PPD logs.' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:28:22

US3322409

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:19:05

[Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15,17,19,20NOV2020 is recorded under Illness Visit Day 3,5,7,9in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6) (b) (4)	04 Dec 2020 11:47:05
	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:39:03

**US3322409**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:02:29
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:39:03

US3322409

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:19:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (u) (+), (b) (6)	28 Jan 2021 21:29:29
User closed query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 15NOV2020 is reported in PPD central lab with 16NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).		22 Jan 2021 16:12:36
Query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 15NOV2020 is reported in PPD central lab with 16NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'initial entry by source enterer was incorrect' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:18:18
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:18:00
User entered '16 Nov 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:18:00
User opened query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 15NOV2020 is reported in PPD central lab with 16NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:47:01
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:02:32
User entered '15 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:39:03



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**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User accepted default value 'Day 5 (Day 5)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34

**US3322409**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:49:57
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34

US3322409

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:19:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User closed query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 17NOV2020 is reported in PPD central lab with 18NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:13:12
Query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 17NOV2020 is reported in PPD central lab with 18NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'date is correct as entered' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:18:39
User opened query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 17NOV2020 is reported in PPD central lab with 18NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:48:45
User closed query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 17NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:48:40
Query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 17NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'only information available in source is number 1F605059282 date shipped 18-nov-2020' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 17:03:08

**US3322409**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: Day 5 sample dated 17NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	10 Jan 2021 10:42:03
		20 Nov 2020 17:49:59
User entered '17 Nov 2020'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34

**US3322409**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User accepted default value 'Day 7 (Day 7)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:19:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:00:52
DataPoint Verified.		20 Nov 2020 17:41:23
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'done' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:23:35
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	20 Nov 2020 17:23:25
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 16:51:08
User closed query 'Data is required. Please complete.' (Site from System).		20 Nov 2020 16:50:37
Query 'Data is required. Please complete.' answered with 'Visit has not happened yet' (Site from System).	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:46
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:33:34
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34

US3322409

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:19:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User closed query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 19NOV2020 is reported in PPD central lab with 20NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 16:13:20
Query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 19NOV2020 is reported in PPD central lab with 20NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'date is correct per source' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:18:54
User opened query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 19NOV2020 is reported in PPD central lab with 20NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:49:30
User closed query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 19NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:49:25
Query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 19NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'only information available in source is number 1F605059282 date shipped 24-nov-2020' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 17:03:50

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:19:05

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 19NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	10 Jan 2021 10:42:27
		20 Nov 2020 17:47:08
User entered '19 Nov 2020' reason for change: New Information	Elisa Moralez (b) (4)	20 Nov 2020 17:23:25
User entered empty.	(b) (4)	
	Frances Saubon (b) (4)	19 Nov 2020 16:33:34
	(b) (4)	



**US3322409**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User accepted default value 'Day 9 (Day 9)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:19:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:29:29
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).		23 Nov 2020 16:07:28
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'done' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:14:40
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	23 Nov 2020 15:14:33
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 16:51:16
User closed query 'Data is required. Please complete.' (Site from System).		20 Nov 2020 16:51:13
Query 'Data is required. Please complete.' answered with 'Visit has not happened yet' (Site from System).	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:50
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:33:34
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34

US3322409

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:19:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:29:29
User closed query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 20NOV2020 is reported in PPD central lab with 22NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).		22 Jan 2021 16:13:34
Query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 20NOV2020 is reported in PPD central lab with 22NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'date is correct per source' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:19:10
User opened query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 20NOV2020 is reported in PPD central lab with 22NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:50:03
User closed query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 20NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD.' (Site from DM).		18 Jan 2021 04:49:59
Query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 20NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD.' answered with 'not available in source' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 17:04:17

US3322409

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:19:05

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: Day 9 sample dated 20NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 10:42:55
User entered '20 Nov 2020' reason for change: New Information	Elisa Moralez (b) (4)	23 Nov 2020 15:14:33
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34

**US3322409**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User accepted default value 'Day 14 (Day 14)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:19:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:29:29
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).		01 Dec 2020 17:49:27
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'done' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 15:59:06
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 15:59:01
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 16:51:29
User closed query 'Data is required. Please complete.' (Site from System).		20 Nov 2020 16:51:24
Query 'Data is required. Please complete.' answered with 'Visit has not happened yet' (Site from System).	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:55
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:33:34
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34

US3322409

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:19:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:29:29
User closed query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 25NOV2020 is reported in PPD central lab with 27NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).		22 Jan 2021 16:14:10
Query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 25NOV2020 is reported in PPD central lab with 27NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with 'date is correct per source' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:19:32
User opened query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 25NOV2020 is reported in PPD central lab with 27NOV2020 date. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 04:50:38
User closed query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 25NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD.' (Site from DM).		18 Jan 2021 04:50:34
Query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 25NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD.' answered with 'only information available in source is number 1F605059282 date shipped 30-nov-2020' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 17:04:42

US3322409

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:19:05

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: Day 14 sample dated 25NOV2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 10:43:19
User closed query 'Per GCL Lab Reconciliation: Saliva : Sample dated "04DEC2020" is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).		14 Dec 2020 09:27:12
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated "04DEC2020" is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'done' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:44:30
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated "04DEC2020" is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 08:46:02
User entered '25 Nov 2020' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 15:59:01
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34



**US3322409**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:19:05**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User accepted default value 'Day 21 (Day 21)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34

US3322409

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:19:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:29:29
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).		14 Dec 2020 14:33:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:44:22
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'Data is not yet available' (Site from DM).	Frances Saubon (b) (4) (b) (4)	03 Dec 2020 16:58:59
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 16:51:37
User closed query 'Data is required. Please complete.' (Site from System).		20 Nov 2020 16:51:34
Query 'Data is required. Please complete.' answered with 'Visit has not happened yet' (Site from System).	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:34:08
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:33:34
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34

**US3322409**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (6)**

**Generated On: 11 Aug 2021 22:19:05**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:29:29
User entered '04 Dec 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4)	11 Dec 2020 14:44:22
User entered empty.	(b) (4) Frances Saubon (b) (4)	19 Nov 2020 16:33:34

**US3322409**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:19:05**

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User accepted default value 'Day 28 (Day 28)'	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34

US3322409

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:19:05

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:29:29
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).		14 Dec 2020 14:34:02
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:44:56
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'Data is not yet available' (Site from DM).	Frances Saubon (b) (4) (b) (4)	03 Dec 2020 16:59:08
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 16:51:49
User closed query 'Data is required. Please complete.' (Site from System).		20 Nov 2020 16:51:44
Query 'Data is required. Please complete.' answered with 'Visit has not happened yet' (Site from System).	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:34:11
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 16:33:34
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Nov 2020 16:33:34

**US3322409**

**Folder: Illness Visit (1)**

**Form: Saliva Collection (7)**

**Generated On: 11 Aug 2021 22:19:05**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:24
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 21:29:29
User entered '09 Dec 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4)	11 Dec 2020 14:44:56
User entered empty.	(b) (4) Frances Saubon (b) (4)	19 Nov 2020 16:33:34

**US3322409**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:14
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:37:55

**US3322409**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:14
User entered '13 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:37:55



US3322409

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:19:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:14
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:37:55

**US3322409**

**Folder: Illness Visit Day 1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:48
User entered 'SICKD1'	System	16 Nov 2020 15:37:55

**US3322409**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:46
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:38:31

US3322409

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:46
User entered '13 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:38:31

**US3322409**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:46
User entered '15:20'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:38:31

**US3322409**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User entered '13 Nov 2020 15:20'	System	16 Nov 2020 15:38:31

US3322409

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:46
User entered '62' in	Elisa Moralez (b) (4)	16 Nov 2020 15:38:31
DataPoint set to visible.	(b) (4) System	16 Nov 2020 15:37:55

US3322409

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:46
User entered '118' lb	Elisa Moralez (b) (4)	16 Nov 2020 15:38:31
DataPoint set to visible.	(b) (4) System	16 Nov 2020 15:37:55



US3322409

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:46
User entered '99.1' F	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:38:31

US3322409

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:46
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:38:31

**US3322409**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:46
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:38:31

**US3322409**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:46
User entered '74'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:38:31

**US3322409**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User entered 'bpm'	System	16 Nov 2020 15:38:31

US3322409

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:46
User entered '12'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:38:31

**US3322409**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User entered 'breaths/min'	System	16 Nov 2020 15:38:31

US3322409

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:46
User entered '129'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:38:31



**US3322409**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User entered 'mmHg'	System	16 Nov 2020 15:38:31

**US3322409**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:38:46
User entered '73'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:38:31

US3322409

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52
User entered 'mmHg'	System	16 Nov 2020 15:38:31

US3322409

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52

**US3322409**

**Folder: Illness Visit Day 1 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:52

US3322409

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:40:14
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:38:37

US3322409

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:40:14
User entered '13 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:38:37

US3322409

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:19:05

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:40:39
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:38:43



**US3322409**

**Folder: Illness Visit Day 1 (1)**

**Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection**

**Generated On: 11 Aug 2021 22:19:05**

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:15:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:40:39
User entered '13 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:38:43

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:19:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:39:51
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:45:14

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:19:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:39:51
User entered '09 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:45:14

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:19:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:39:51
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:45:14

**US3322409**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:05
User entered 'SICKD28'	System	11 Dec 2020 14:45:14

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:40:43
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:45:58

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:40:43
User entered '09 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:45:58

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:40:43
User entered '14:34'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:45:58



US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User entered '09 Dec 2020 14:34'	System	11 Dec 2020 14:45:58

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:40:43
User entered '62' in	Elisa Moralez (b) (4)	11 Dec 2020 14:45:58
DataPoint set to visible.	(b) (4) System	11 Dec 2020 14:45:14

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:40:43
User entered '116' lb	Elisa Moralez (b) (4)	11 Dec 2020 14:45:58
DataPoint set to visible.	(b) (4) System	11 Dec 2020 14:45:14

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:40:43
User entered '98.3' F	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:45:58

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:40:43
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:45:58

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:40:43
User entered empty.	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:45:58

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:40:43
User entered '74'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:45:58

**US3322409**

**Folder: Convalescence Visit Day 28 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User entered 'bpm'	System	11 Dec 2020 14:45:58



US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:40:43
User entered '14'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:45:58

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User entered 'breaths/min'	System	11 Dec 2020 14:45:58

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:40:43
User entered '138'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:45:58

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User entered 'mmHg'	System	11 Dec 2020 14:45:58

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:40:43
User entered '80'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:45:58

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08
User entered 'mmHg'	System	11 Dec 2020 14:45:58

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:08



US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:40:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:46:06

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:12
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:40:59
User entered '09 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:46:06

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:19:05

[Was Blood Sample Taken for Immunologic Assessment of SARS\\_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:41:14
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:46:15

US3322409

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 22:19:05

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 18:16:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 09 DEC 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 09:21:11
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 09 DEC 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Noted, information will be updated once available. Thank you' (Site from DM).	Frances Saubon (b) (4) (b) (4)	24 Dec 2020 03:27:15
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 09 DEC 2020 is recorded under Convalescence Visit Day 28 visit in EDC, however the same SARS-CoV-2 serum sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 05:39:49
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 19:41:14
User entered '09 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	11 Dec 2020 14:46:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:19:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:41:43
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 17:40:36

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:19:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:41:43
User entered '18 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 17:40:36

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:41:43
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 17:40:36

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 17:40:36



US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:19:05

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:45:41
User entered '18 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 17:40:51

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:19:05**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:39:58

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:19:05

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:45:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 17:40:51

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:19:05**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:39:58

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:19:05

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:45:41
User entered '18 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 17:40:51

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:19:05

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:45:41
User entered 'Placebo (Placebo)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 17:40:51

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:19:05**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:45:41
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 05:08:53
User entered 'Placebo (Placebo)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 17:40:51

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:19:05**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:45:41
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 05:08:53
User entered 'Placebo (Placebo)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 17:40:51



US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:19:05

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:45:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 17:40:51

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:19:05**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered '1'	System	18 Jan 2021 17:40:51

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'I'	System	18 Jan 2021 17:40:51

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:19:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:19:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:19:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered empty.	System	18 Jan 2021 20:49:15
DataPoint set to visible.	System	18 Jan 2021 17:40:51

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:19:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:19:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15



US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:19:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered empty.	System	18 Jan 2021 20:49:15
DataPoint set to visible.	System	18 Jan 2021 17:40:51

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered '18 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered '10:42'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered '18 Jan 2021 10:42'	System	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered '98.2' F	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered '77'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'bpm'	System	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered '17'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'breaths/min'	System	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered '124'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'mmHg'	System	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered '82'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15



**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'mmHg'	System	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:19:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:19:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:19:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered empty.	System	18 Jan 2021 20:49:15
DataPoint set to visible.	System	18 Jan 2021 17:40:51

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered '18 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Jan 2021 20:49:25
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Jan 2021 20:49:25
User entered '14:43' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:25
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Jan 2021 20:49:15
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15



**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered '18 Jan 2021 14:43'	System	18 Jan 2021 20:49:25
User entered empty.	System	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Jan 2021 20:49:25
Query 'Data is required. Please provide.' answered by System data change (Site from System).		18 Jan 2021 20:49:25
User entered '98.5' F reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:25
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Jan 2021 20:49:15
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered '76'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'bpm'	System	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered '17'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'breaths/min'	System	18 Jan 2021 20:49:15



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered '117'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'mmHg'	System	18 Jan 2021 20:49:15

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:46:58
User entered '82'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:15

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'mmHg'	System	18 Jan 2021 20:49:15

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:33

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:16
User entered '18 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:33

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:26
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:52

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:26
User entered '18 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:52



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:26
User entered 'Urine (URINE)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:52

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:26
User entered 'Negative (NEGATIVE)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:52

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:26
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:52

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:26
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:52

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:26
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:49:52

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered empty.	System	18 Jan 2021 20:49:52

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:41
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:50:06

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:41
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:50:06



US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:41
User entered empty.	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:50:06

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'mRNA-1273'	System	18 Jan 2021 20:50:06
DataPoint set to visible.	System	18 Jan 2021 17:40:51

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:41
User entered '18 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:50:06

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:41
User entered '14:06'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:50:06

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:19:05**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered '18 Jan 2021 14:06'	System	18 Jan 2021 20:50:06

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:41
User entered 'Left Arm (LEFT ARM)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:50:06

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:19:05**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		25 Feb 2021 22:47:41
User entered 'ONCE'	System	18 Jan 2021 20:50:06

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:19:05**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'INTRAMUSCULAR'	System	18 Jan 2021 20:50:06



US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:19:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:58
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:50:13

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:19:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:58
User entered '18 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:50:13

US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:19:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:47:58
User entered '13:39'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:50:13

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered '18 Jan 2021 13:39'	System	18 Jan 2021 20:50:13

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:19:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:48:11
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:50:21

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:48:11
User entered '18 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:50:21

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:19:05**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:48:11
User entered '13:34'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:50:21

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:19:05**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered '18 Jan 2021 13:34'	System	18 Jan 2021 20:50:21



US3322409

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:48:18
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 20:50:25

**US3322409**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered '1'	System	18 Jan 2021 20:50:25

**US3322409**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:49:16
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	29 Jan 2021 20:05:59

**US3322409**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:49:16
User entered '26 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	29 Jan 2021 20:05:59

**US3322409**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:49:16
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	29 Jan 2021 20:05:59

US3322409

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:19:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:49:16
User entered empty.	Elisa Moralez (b) (4) (b) (4)	29 Jan 2021 20:05:59

**US3322409**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:49:21
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	29 Jan 2021 20:05:48

**US3322409**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'I'	System	29 Jan 2021 20:05:48



**US3322409**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered '1'	System	29 Jan 2021 20:05:48
DataPoint set to visible.	System	29 Jan 2021 20:05:48

**US3322409**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 22:49:40
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	12 Feb 2021 21:18:10

US3322409

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:19:05

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User closed query 'Please add OL-Day 36 completed on 22Feb21 as source is available. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 06:10:04
Query 'Please add OL-Day 36 completed on 22Feb21 as source is available. Thank you.' answered with 'already entered' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:43:41
User opened query 'Please add OL-Day 36 completed on 22Feb21 as source is available. Thank you.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 22:55:53
DataPoint Verified.		25 Feb 2021 22:49:40
User entered '12 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:18:10

**US3322409**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:49:40
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:18:10

**US3322409**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'OLD29'	System	12 Feb 2021 21:18:10

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered '12 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00



**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered '11:26'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered '12 Feb 2021 11:26'	System	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered '98.1' F	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered '76'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'bpm'	System	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered '17'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00



**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'breaths/min'	System	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered '137'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'mmHg'	System	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered '76'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'mmHg'	System	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered '12 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00



**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered '13:10'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered '12 Feb 2021 13:10'	System	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered '98.4' F	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered '65'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'bpm'	System	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered '17'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00



**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'breaths/min'	System	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered '124'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

**US3322409**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'mmHg'	System	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:22
User entered '80'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:19:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'mmHg'	System	12 Feb 2021 21:19:00

US3322409

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:07

US3322409

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:34
User entered '12 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:07

**US3322409**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:59
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:20



**US3322409**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:59
User entered '12 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:20

US3322409

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:59
User entered 'Urine (URINE)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:20

**US3322409**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:59
User entered 'Negative (NEGATIVE)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:20

US3322409

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:19:05

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:59
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:20

**US3322409**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:59
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:20

**US3322409**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:50:59
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:20

**US3322409**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered empty.	System	12 Feb 2021 21:19:20

**US3322409**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:19:05**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:51:19
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:32



US3322409

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:51:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:32

US3322409

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:51:19
User entered empty.	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:32

US3322409

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'mRNA-1273'	System	12 Feb 2021 21:19:32
DataPoint set to visible.	System	29 Jan 2021 20:05:48

US3322409

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:51:19
User entered '12 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:32

US3322409

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:51:19
User entered '12:33'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:32

**US3322409**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:19:05**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered '12 Feb 2021 12:33'	System	12 Feb 2021 21:19:32

**US3322409**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:19:05**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:51:19
User entered 'Left Arm (LEFT ARM)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:32

**US3322409**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:19:05**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		25 Feb 2021 22:51:19
User entered 'ONCE'	System	12 Feb 2021 21:19:32



US3322409

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:19:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'INTRAMUSCULAR'	System	12 Feb 2021 21:19:32

US3322409

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:19:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:51:22
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	12 Feb 2021 21:19:46

**US3322409**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'I'	System	12 Feb 2021 21:19:46

**US3322409**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 06:10:21
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	02 Mar 2021 19:55:02

**US3322409**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 06:10:21
User entered '22 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	02 Mar 2021 19:55:02

**US3322409**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 06:10:21
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4) (b) (4)	02 Mar 2021 19:55:02

**US3322409**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:19:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 06:10:21
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Mar 2021 19:55:02

**US3322409**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 06:10:27
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	02 Mar 2021 19:54:54



**US3322409**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:19:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'I'	System	02 Mar 2021 19:54:54

US3322409

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:19:05

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:50:42
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:20

**US3322409**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:50:42
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '12 Mar 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:20

**US3322409**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:50:42
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Clinic (Clinic)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:20

**US3322409**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:19:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered 'OLD57'	System	12 Mar 2021 20:56:20

**US3322409**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:55:05
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:41

US3322409

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:55:05
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:41

**US3322409**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:55:05
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:41



**US3322409**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered empty.	System	12 Mar 2021 20:56:41

US3322409

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:55:05
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:41

**US3322409**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:55:05
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:41

**US3322409**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:55:05
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:41

**US3322409**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:55:05
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:41

**US3322409**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered empty.	System	12 Mar 2021 20:56:41

US3322409

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:19:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:55:05
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:41

**US3322409**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered empty.	System	12 Mar 2021 20:56:41



**US3322409**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:55:05
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:41

**US3322409**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered empty.	System	12 Mar 2021 20:56:41

**US3322409**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:55:05
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:41

**US3322409**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered empty.	System	12 Mar 2021 20:56:41

**US3322409**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20

**US3322409**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:19:05**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20

US3322409

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:51:01
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:47

US3322409

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:19:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:51:03
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:47



US3322409

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:19:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:51:23
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:55

US3322409

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:19:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:51:23
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '12 Mar 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:55

**US3322409**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:19:05**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
DataPoint Verified.		13 Apr 2021 16:51:23
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '12:49'	(b) (4) Elisa Moralez (b) (4) (b) (4)	12 Mar 2021 20:56:55

**US3322409**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:19:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:34:20
User entered '12 Mar 2021 12:49'	System	12 Mar 2021 20:56:55

US3322409

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:19:05

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:55:58
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User closed query 'Per source Tennis elbow and headaches from eye strain are noted. Please consider adding as AE.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:20:25
Query 'Per source Tennis elbow and headaches from eye strain are noted. Please consider adding as AE.' answered with 'AEs for this patient are "Shingles - Left foot/ankle," "Dog Bite (Left/Right Thigh)," "Symptomatic COVID-19," and "Positive pregnancy test" per source, which are all entered already' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 20:31:34
User opened query 'Per source Tennis elbow and headaches from eye strain are noted. Please consider adding as AE.' (Site from CRA).	(b) (4), (b) (6)	02 Mar 2021 22:00:37
Query 'Per source headaches from eye strain and Tennis elbow are captured. Please confirm or clarify.' canceled (Site from CRA).		02 Mar 2021 21:50:56
User opened query 'Per source headaches from eye strain and Tennis elbow are captured. Please confirm or clarify.' (Site from CRA).		25 Feb 2021 22:24:57
DataPoint Verified.		20 Nov 2020 18:17:49
User entered 'Yes (Y)'		19 Oct 2020 22:27:07
	Frances Saubon (b) (4) (b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes zoster, LLT: Shingles - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:32:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:32:29
Data point term sent to Coder	System	19 Oct 2020 22:30:55
User entered 'Shingles - Left foot/ankle'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02



US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '11 Oct 2020'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:19:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 22:30:02

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:19:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:19:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 22:30:02



**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02



US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'None (NONE)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:19:05**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
Signature has been broken.	(b) (4)	
	Moez Talpur (b) (4)	26 Mar 2021 20:59:59
	(b) (4)	
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Frances Saubon (b) (4)	19 Oct 2020 22:30:02
	(b) (4)	



US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'I'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 22:30:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 22:30:15
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:15
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 22:30:02
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

US3322409

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:19:05

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:30:02

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Oct 2020 22:30:02

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 22:30:02

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Animal bite, LLT: Dog bite - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:23:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:23:13
Data point term sent to Coder	System	02 Nov 2020 22:06:42
User entered 'dog bite (left/right thigh)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '23 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User entered empty.	System	02 Nov 2020 22:05:56

US3322409

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56



**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '23 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User entered empty.	System	02 Nov 2020 22:05:56

US3322409

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

US3322409

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

US3322409

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56



US3322409

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

US3322409

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

US3322409

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

US3322409

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

US3322409

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56



US3322409

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'None (NONE)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

US3322409

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'l'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56

US3322409

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:19:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:05:56



**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User entered '0'	System	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46
User entered 'I'	System	02 Nov 2020 22:05:56

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:46

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

[AEID](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
Reviewed for Safety.		17 Nov 2020 14:48:43
User entered 'USA-US060-2020-mRNA-1273-P301000011'	System	17 Nov 2020 14:48:38
User entered 'New'	(b) (4), (b) (6)	17 Nov 2020 14:48:38

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Nov 2020 21:38:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:27
Data point term sent to Coder	System	23 Nov 2020 14:59:40
User closed query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	System	23 Nov 2020 14:59:00
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' answered with 'Per eCRF guidelines page 36: patients who has had symptoms and a confirmed positive PCR for Covid-19, "the AE Term MUST be entered as 'SYMPTOMATIC COVID-19' ' (Site from System).	Frances Saubon (b) (4)	23 Nov 2020 14:59:00
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding. ' (Site from System).	Coder Import (b) (4)	23 Nov 2020 12:24:25
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:21:37
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	16 Nov 2020 16:09:49

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	16 Nov 2020 16:09:49
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	16 Nov 2020 16:09:05
User entered 'Symptomatic COVID-19' reason for	Frances Saubon (b) (4)	16 Nov 2020 16:08:49
change: Data Entry Error	(b) (4)	
Data point term sent to Coder	System	16 Nov 2020 15:49:29
User entered 'Confirmed COVID-19 positive case'	Elisa Moralez (b) (4)	16 Nov 2020 15:49:01
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:45:34
DataPoint Un-verified.	Frances Saubon (b) (4)	23 Nov 2020 15:00:40
User entered '07 Nov 2020' reason for change: New Information	(b) (4) Frances Saubon (b) (4)	23 Nov 2020 15:00:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '05 Nov 2020' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Nov 2020 16:08:49
User entered '5 Nov 2020'	(b) (4) Elisa Moralez (b) (4)	16 Nov 2020 15:49:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
DataPoint Verified.	System	23 Nov 2020 15:00:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Nov 2020 18:21:37
Query 'Data is required. Please provide.' answered with 'not available in source' (Site from System).	(b) (4)	17 Nov 2020 15:32:02
User opened query 'Data is required. Please provide.' (Site from System).	Elisa Moralez (b) (4)	16 Nov 2020 15:49:13
User entered empty.	(b) (4)	
	System	16 Nov 2020 15:49:01
	Elisa Moralez (b) (4)	16 Nov 2020 15:49:01
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User entered empty.	System	16 Nov 2020 15:49:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:45:34
DataPoint Un-verified.	Frances Saubon (b) (4)	23 Nov 2020 15:00:40
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Frances Saubon (b) (4)	23 Nov 2020 15:00:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:14:27
User closed query 'Per source end date updated to 04Dec2020. Please confirm with source and update accordingly.' (Site from CRA).		23 Mar 2021 03:14:17
Query 'Per source end date updated to 04Dec2020. Please confirm with source and update accordingly.' answered with 'updated, thanks' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 14:59:54
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 14:59:46
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 14:59:46
User entered '04 Dec 2020' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	17 Mar 2021 14:59:46
User opened query 'Per source end date updated to 04Dec2020. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 18:41:20
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:16:24
User closed query 'PV Query: The event end date is reported as 22 Nov 2020; however, symptoms were still reported on that day. Please clarify event stop date; stop date should be when all symptoms have resolved (no symptoms reported on 23 Nov 2020).' (Site from Safety).		12 Jan 2021 14:38:06
Query 'PV Query: The event end date is reported as 22 Nov 2020; however, symptoms were still reported on that day. Please clarify event stop date; stop date should be when all symptoms have resolved (no symptoms reported on 23 Nov 2020).' answered with 'done' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 17:05:24
User entered '23 Nov 2020' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 17:05:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: The event end date is reported as 22 Nov 2020; however, symptoms were still reported on that day. Please clarify event stop date; stop date should be when all symptoms have resolved (no symptoms reported on 23 Nov 2020).' (Site from Safety).	(b) (4), (b) (6)	07 Jan 2021 19:31:28
User closed query 'PV Query: Please clarify event end date (when all symptoms resolved). It has been reported the subject still experienced mild headache on 22 Nov 2020.' (Site from Safety).		30 Dec 2020 22:21:02
Query 'PV Query: Please clarify event end date (when all symptoms resolved). It has been reported the subject still experienced mild headache on 22 Nov 2020.' answered with 'that is the date currently entered' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	29 Dec 2020 18:03:59
User opened query 'PV Query: Please clarify event end date (when all symptoms resolved). It has been reported the subject still experienced mild headache on 22 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 17:19:10
User closed query 'PV Query: Please clarify event end date as 14 Nov 2020 as the subject reported headache on 15 Nov and 22 Nov 2020.' (Site from Safety).		21 Dec 2020 20:04:28
Query 'PV Query: Please clarify event end date as 14 Nov 2020 as the subject reported headache on 15 Nov and 22 Nov 2020.' answered with 'updated' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	18 Dec 2020 03:04:40
DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	18 Dec 2020 03:04:33
User entered '22 Nov 2020' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	18 Dec 2020 03:04:33
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 19:45:34
User opened query 'PV Query: Please clarify event end date as 14 Nov 2020 as the subject reported headache on 15 Nov and 22 Nov 2020.' (Site from Safety).		08 Dec 2020 20:37:15
User closed query 'PV Query: Please provide the event end date when available.' (Site from Safety).		30 Nov 2020 23:26:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Nov 2020 16:23:42
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	23 Nov 2020 16:23:42
Query 'PV Query: Please provide the event end date when available.' answered with 'updated' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	23 Nov 2020 15:01:54
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	23 Nov 2020 15:00:40
DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	23 Nov 2020 15:00:40
User entered '14 Nov 2020' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	23 Nov 2020 15:00:40
User opened query 'PV Query: Please provide the event end date when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:55:53
DataPoint Verified.		20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User entered empty.	System	16 Nov 2020 15:49:01

US3322409

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

[Severity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Death](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

[Life threatening](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Not Related (NOT RELATED)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'Not Applicable (NOT APPLICABLE)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[None](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

US3322409

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:45:34
User closed query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).		30 Nov 2020 23:27:20
Query 'PV Query: Please provide the final event outcome, when available.' answered with 'updated' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	23 Nov 2020 16:23:58
DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	23 Nov 2020 16:23:42
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	23 Nov 2020 16:23:42
User opened query 'PV Query: Please provide the final event outcome, when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:56:16
DataPoint Verified.		20 Nov 2020 18:21:37
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:01

US3322409

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

[Narrative](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User closed query 'PV query: Please confirm shingles and dog bite meet criteria of AE/SAE. If not, please explain.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 20:12:43
User closed query 'PV Query: Treatment for the event included oral guaifenesin started on 06 Nov 2020 which is before the onset date of the event (07 Nov 2020). Please confirm the event onset date.' (Site from Safety).		21 Dec 2020 20:12:40
Query 'PV Query: Treatment for the event included oral guaifenesin started on 06 Nov 2020 which is before the onset date of the event (07 Nov 2020). Please confirm the event onset date.' answered with 'please see updated log thank you' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	21 Dec 2020 16:33:12
Query 'PV query: Please confirm shingles and dog bite meet criteria of AE/SAE. If not, please explain.' answered with 'Please refer to the complete AE log. Shingles and dog bite has already been listed as an AE.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	18 Dec 2020 03:07:55
User opened query 'PV query: Please confirm shingles and dog bite meet criteria of AE/SAE. If not please explain.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 20:38:04
User opened query 'PV Query: Treatment for the event included oral guaifenesin started on 06 Nov 2020 which is before the onset date of the event (07 Nov 2020). Please confirm the event onset date.' (Site from Safety).		08 Dec 2020 20:36:43
User closed query 'PV Query: Please provide the dates and results for Covid-19 testing.' (Site from Safety).		30 Nov 2020 23:27:32
Query 'PV Query: Please provide the dates and results for Covid-19 testing.' answered with 'Dates and results for Covid-19 testing is indicated under Covid-19 Assessment folder.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	23 Nov 2020 18:23:21
User opened query 'PV Query: Please provide the dates and results for Covid-19 testing.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 13:56:39

US3322409

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:19:05

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:21:37
User entered empty; reason for change Data Entry Error	Frances Saubon (b) (4)	16 Nov 2020 16:08:49
User entered 'the nasal swab from C2 visit (05-Nov-2020) came back positive even before patient came for illness visit'	Elisa Moralez (b) (4)	16 Nov 2020 15:49:01



**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User entered '0'	System	16 Nov 2020 15:49:01

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47
User entered 'I'	System	16 Nov 2020 15:49:01

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 13:33:52
Data hard locked.		29 Apr 2021 13:33:47

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:19:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Epicondylitis, LLT: Tennis elbow - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	09 Mar 2021 18:18:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:18:38
Data point term sent to Coder	System	09 Mar 2021 18:18:00
User entered 'Tennis elbow'	Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

US3322409

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:19:05

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45



**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '09 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
User entered empty.	System	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '15 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4)	
	Elisa Moralez (b) (4)	09 Mar 2021 18:17:45
	(b) (4)	

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
User entered empty.	System	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45



US3322409

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:19:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

US3322409

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:19:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

US3322409

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:19:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

US3322409

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:19:05

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:19:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

US3322409

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:19:05

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Not Related (NOT RELATED)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

US3322409

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:19:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

US3322409

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:19:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'l'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45



US3322409

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:19:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
DataPoint Verified.		13 Apr 2021 16:45:36
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
User entered '0'	System	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57
User entered 'I'	System	09 Mar 2021 18:17:45

**US3322409**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:33:57

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:19:05

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 17:55:58
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User closed query 'Per source Ibuprofen taken starting 15Nov20 ongoing 400 mg QD; Prednisone taken for Tennis elbow from 09Jan21 to 15Jan21 20mg BID.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Mar 2021 03:21:09
Query 'Per source Ibuprofen taken starting 15Nov20 ongoing 400 mg QD; Prednisone taken for Tennis elbow from 09Jan21 to 15Jan21 20mg BID.' answered with 'updated, thank you, there are no records of either condition associated with these two medications in MH or AE in source, and I have asked the CRCs who saw those patients to add them. They will be entered as soon as they are available. thank you.' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:35:46
User opened query 'Per source Ibuprofen taken starting 15Nov20 ongoing 400 mg QD; Prednisone taken for Tennis elbow from 09Jan21 to 15Jan21 20mg BID.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 22:23:37
DataPoint Verified.		20 Nov 2020 18:21:47
User entered 'Yes (Y)'		02 Oct 2020 22:02:35



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
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) (b) (4)	02 Oct 2020 22:05:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 22:05:57
Data point term sent to Coder	System	02 Oct 2020 22:05:01
User entered 'Multivitamin'	(b) (4), (b) (6)	02 Oct 2020 22:04:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:19:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 22:45:00
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:52:39
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'done' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 16:00:04
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 15:59:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 15:59:55
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 08:36:43
DataPoint Verified.		20 Nov 2020 18:25:55
User entered 'No (N)'		02 Oct 2020 22:04:19

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'supplement'		02 Oct 2020 22:04:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:19:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
Signature has been broken.	(b) (4) Moez Talpur (b) (4)	26 Mar 2021 20:59:50
User signature succeeded.	(b) (4) Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'I'		02 Oct 2020 22:04:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:19:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'tablet (TABLET)'		02 Oct 2020 22:04:19

US3322409

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:19:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.		02 Oct 2020 22:04:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:19:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'once daily (QD)'		02 Oct 2020 22:04:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.		02 Oct 2020 22:04:19



US3322409

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Oral (ORAL)'		02 Oct 2020 22:04:19

US3322409

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:19:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.		02 Oct 2020 22:04:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:19:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'UN Jan 2020'		02 Oct 2020 22:04:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:19:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '0'		02 Oct 2020 22:04:19

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Yes (Y)'		02 Oct 2020 22:04:19

US3322409

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:19:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.		02 Oct 2020 22:04:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:19:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 22:04:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 22:04:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Oct 2020 22:04:28
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 22:04:19
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 22:04:19

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 22:04:19



US3322409

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Oct 2020 22:04:19

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Oct 2020 22:04:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
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: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:06:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:06:20
Data point term sent to Coder	System	03 Nov 2020 15:05:26
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	03 Nov 2020 15:04:39
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: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:14:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:14:42
Data point term sent to Coder	System	07 Oct 2020 14:05:35
User entered 'Naproxen'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 14:04:58

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:19:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 14:04:58

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:19:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MUSCLE ACHES 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 MUSCLE ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:36:51
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MUSCLE ACHES 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 MUSCLE ACHES did not meet the AE reporting criteria. ' answered with 'DOES NOT MEET AE CRITERIA' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	14 Dec 2020 15:39:13

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:19:05

[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 MUSCLE ACHES 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 MUSCLE ACHES did not meet the AE reporting criteria. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	14 Dec 2020 04:57:52
	(b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'MUSCLE aches' reason for change: New Information	Elisa Moralez (b) (4)	03 Nov 2020 15:04:39
User entered 'Muscle pain'	(b) (4)	
	Frances Saubon (b) (4)	07 Oct 2020 14:04:58
	(b) (4)	

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '220'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 14:04:58

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:19:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 14:04:58



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:19:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 14:04:58

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:19:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'once (ONCE)'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 14:04:58

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 14:04:58

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 14:04:58

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:19:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 14:04:58

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:19:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '4 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	03 Nov 2020 15:04:39
User entered '03 Oct 2020'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 14:04:58

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:19:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '0'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 14:04:58

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 14:04:58



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '4 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	03 Nov 2020 15:04:39
User entered '03 Oct 2020'	Frances Saubon (b) (4) (b) (4)	07 Oct 2020 14:04:58

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:19:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MUSCLE 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 MUSCLE PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:18:30
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the MUSCLE 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 MUSCLE PAIN did not meet the AE reporting criteria.' answered with 'does not meet AE reporting criteria' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 16:00:46

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:19:05

[Was this medication taken for solicited event?](#)

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 MUSCLE 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 MUSCLE PAIN did not meet the AE reporting criteria.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 08:44:41
	(b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Yes (Y)'	Frances Saubon (b) (4)	07 Oct 2020 14:04:58
	(b) (4)	

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User entered empty.	System	07 Oct 2020 14:04:58

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User entered empty.	System	07 Oct 2020 14:04:58

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:29
User entered empty.	System	07 Oct 2020 14:04:58

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: NON-SELECTIVE MONOAMINE REUPTAKE INHIBITORS, PRODUCT: NORTRIPTYLINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:10:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:10:31
Data point term sent to Coder	System	19 Oct 2020 22:31:58
User entered 'Nortriptyline'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:19:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:19:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 08:19:37
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'This medication was prescribed by the patient's PCP, it can be used as a pain medication to treat neuropathic pain. Shingles causes neuropathic type pain.' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 17:58:01
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 08:46:46
DataPoint Verified.		20 Nov 2020 18:25:55
User entered 'Shingles'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:19:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '25'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:19:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'mg (mg)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19

US3322409

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:19:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:19:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'once daily (QD)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:19:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19

US3322409

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:19:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:19:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '19 Oct 2020'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:19:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '0'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:19:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:19:05

Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User closed query 'Per CDM: Was this medication taken for solicited event? = YES. However, Shingles is not a solicited event for this study. Please review and update applicable details accordingly. Otherwise, clarify. ' (Site from DM).		12 Nov 2020 15:45:37
Query 'Per CDM: Was this medication taken for solicited event? = YES. However, Shingles is not a solicited event for this study. Please review and update applicable details accordingly. Otherwise, clarify. ' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	11 Nov 2020 20:09:35
User entered 'No (N)' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	11 Nov 2020 20:09:24
User opened query 'Per CDM: Was this medication taken for solicited event? = YES. However, Shingles is not a solicited event for this study. Please review and update applicable details accordingly. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 19:21:59
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:31:19

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 22:31:19

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 22:31:19

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 22:31:19



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: VALACICLOVIR, PRODUCTSYNONYM: VALACYCLOVIR [VALACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:33:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:33:33
Data point term sent to Coder	System	19 Oct 2020 22:32:58
User entered 'Valcyclovir'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:05

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:05

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Shingles'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:05

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:19:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'l'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:05

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'g (g)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:05

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:19:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:05

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'other (OTHER)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:05

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '1 gm now & 1 tab PO daily x 7 days'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:05



**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Oral (ORAL)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:05

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:19:05**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:05

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '19 Oct 2020'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:05

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:19:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '0'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:05

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	03 Nov 2020 15:05:10
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:05

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '26 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	03 Nov 2020 15:05:10
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:05

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:19:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User closed query 'Per CDM: Was this medication taken for solicited event? = YES. However, Shingles is not a solicited event for this study. Please review and update applicable details accordingly. Otherwise, clarify.' (Site from DM).		12 Nov 2020 15:45:51
Query 'Per CDM: Was this medication taken for solicited event? = YES. However, Shingles is not a solicited event for this study. Please review and update applicable details accordingly. Otherwise, clarify.' answered with 'updated' (Site from DM).	Frances Saubon (b) (4)	11 Nov 2020 20:10:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	11 Nov 2020 20:10:32
User opened query 'Per CDM: Was this medication taken for solicited event? = YES. However, Shingles is not a solicited event for this study. Please review and update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 19:21:13
User entered 'Yes (Y)'	Frances Saubon (b) (4)	19 Oct 2020 22:32:05

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User entered empty.	System	19 Oct 2020 22:32:05



**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User entered empty.	System	19 Oct 2020 22:32:05

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:32
User entered empty.	System	19 Oct 2020 22:32:05

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:19:29
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: CHEMOTHERAPEUTICS FOR TOPICAL USE, ATC: ANTIVIRALS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 06:38:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 06:38:21
Data point term sent to Coder	System	30 Nov 2020 18:05:58
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 18:05:28
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 18:05:28
User entered 'ACYCLOVIR (5%)' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 18:05:28
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:25:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 23:53:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 23:53:28
Data point term sent to Coder	System	19 Oct 2020 22:32:58
User entered 'Acyclovir'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:19:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Shingles'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:19:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:19:06
User closed query 'Per DM CLR: Note, 5% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1 application, etc). Update as appropriate.' (Site from DM).		01 Dec 2020 19:58:28
Query 'Per DM CLR: Note, 5% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1 application, etc). Update as appropriate.' answered with 'done, thanks' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 18:05:34
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 18:05:28
User entered '1' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	30 Nov 2020 18:05:28
User opened query 'Per DM CLR: Note, 5% is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1 application, etc). Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 08:47:42
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '5'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Other (OTHER)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:19:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:19:20
DataPoint Un-verified.	Elisa Moralez (b) (4)	30 Nov 2020 18:05:28
User entered 'application' reason for change: Per Query Resolution	(b) (4) Elisa Moralez (b) (4)	30 Nov 2020 18:05:28
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'PERCENT'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:19:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'twice daily (BID)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Topical (TOPICAL)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:19:05**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '19 Oct 2020'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '0'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:19:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	03 Nov 2020 15:05:41
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '23 Oct 2020' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	03 Nov 2020 15:05:41
User entered empty.	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:19:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	19 Oct 2020 22:32:41

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User entered '2'	System	19 Oct 2020 22:32:41

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User entered '1'	System	19 Oct 2020 22:32:41

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:35
User entered '804 (804)'	System	19 Oct 2020 22:32:41

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:37:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:37:14
Data point term sent to Coder	System	02 Nov 2020 22:07:45
User entered 'ibuprofen'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:07:31

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:19:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:07:31

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:19:05**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'dog bite'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:07:31

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:19:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '400'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:07:31



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:19:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:07:31

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:19:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:07:31

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:19:05**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'as needed (PRN)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:07:31

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:07:31

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:07:31

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:19:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:07:31

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:19:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
DataPoint Verified.	(b) (4)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:37:27
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates as appropriate. ' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	14 Dec 2020 16:04:51
DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	14 Dec 2020 16:04:36
User entered '23 Oct 2020' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	14 Dec 2020 16:04:36
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 04:59:36
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '18 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:07:31

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:19:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:07:31



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:19:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
DataPoint Verified.	(b) (4)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Un-verified.	(b) (4)	
	Frances Saubon (b) (4)	14 Dec 2020 16:04:36
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4)	
	Frances Saubon (b) (4)	14 Dec 2020 16:04:36
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	02 Nov 2020 22:07:31
	(b) (4)	

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Un-verified.	(b) (4)	
	Frances Saubon (b) (4)	14 Dec 2020 16:04:36
User entered '26 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Frances Saubon (b) (4)	14 Dec 2020 16:04:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4)	02 Nov 2020 22:07:31
	(b) (4)	

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:19:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:07:31

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User entered empty.	System	02 Nov 2020 22:07:31

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User entered empty.	System	02 Nov 2020 22:07:31

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:39
User entered empty.	System	02 Nov 2020 22:07:31

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:19:59
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 15:53:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Dec 2020 15:53:58
Data point term sent to Coder	System	14 Dec 2020 16:06:25
DataPoint Un-verified.	Frances Saubon (b) (4)	14 Dec 2020 16:05:55
Coding entries removed.	(b) (4) Frances Saubon (b) (4)	14 Dec 2020 16:05:55
User entered 'Amoxicillin/Clavulanate potassium' reason for change: Per Query Resolution	(b) (4) Frances Saubon (b) (4)	14 Dec 2020 16:05:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:13:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:13:14
Data point term sent to Coder	System	02 Nov 2020 22:08:46
User entered 'Augmentin 875'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:07

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:19:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:07



**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:19:05**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'dog bite'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:07

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:19:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:20:06
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable. As well as, remove one component dose recorded in the medication name. (e.g., 875/125).' '(Site from DM).		15 Dec 2020 17:38:32
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable. As well as, remove one component dose recorded in the medication name. (e.g., 875/125).' 'answered with 'updated' (Site from DM).	Frances Saubon (b) (4)	14 Dec 2020 16:06:00
DataPoint Un-verified.	(b) (4)	14 Dec 2020 16:05:55
User entered '875 /125' reason for change: Per Query Resolution	Frances Saubon (b) (4)	14 Dec 2020 16:05:55
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable. As well as, remove one component dose recorded in the medication name. (e.g., 875/125).' '(Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:00:04
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '125'	Elisa Moralez (b) (4)	02 Nov 2020 22:08:07

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:19:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:07

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:19:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:07

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:19:05**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'twice daily (BID)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:07

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:19:05**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:07

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:19:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:07

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:19:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:07



**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '23 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:07

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:07

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:19:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:07

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:19:05**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '02 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:07

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:19:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:07

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User entered '2'	System	02 Nov 2020 22:08:07

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User entered '1'	System	02 Nov 2020 22:08:07

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:42
User entered '804 (804)'	System	02 Nov 2020 22:08:07



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:50:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:50:13
Data point term sent to Coder	System	02 Nov 2020 22:08:46
User entered 'Ketorolac'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:19:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:19:05**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'dog bite'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:19:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '10'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:19:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:19:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:19:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'as needed (PRN)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44



**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:19:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '23 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:19:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:19:05**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '26 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:19:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:08:44

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User entered empty.	System	02 Nov 2020 22:08:44



**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User entered empty.	System	02 Nov 2020 22:08:44

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:46
User entered empty.	System	02 Nov 2020 22:08:44

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: MUPIROCIN, PRODUCTSYNONYM: BACTROBAN [MUPIROCIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:13:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:13:15
Data point term sent to Coder	System	02 Nov 2020 22:09:47
User entered 'Bactroban (2%)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:09:27

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:19:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:09:27

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:19:05**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'dog bite'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:09:27

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:19:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'l'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:09:27

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:19:05**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Other (OTHER)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:09:27

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:19:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'application'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:09:27



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:19:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'three times daily (TID)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:09:27

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:09:27

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Topical (TOPICAL)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:09:27

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:19:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:09:27

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '23 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:09:27

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '0'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:09:27

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:19:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:20:32
User closed query 'Per DM CLR: Please review if a stop date if available. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).		18 Dec 2020 20:42:00
Query 'Per DM CLR: Please review if a stop date if available. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'patient has been contacted and data has been updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	18 Dec 2020 02:57:48
DataPoint Un-verified.	Frances Saubon (b) (4) (b) (4)	18 Dec 2020 02:57:29
User entered 'No (N)' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	18 Dec 2020 02:57:29
User opened query 'Per DM CLR: Please review if a stop date if available. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:00:28
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:09:27

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:20:34
DataPoint Un-verified.	Frances Saubon (b) (4)	18 Dec 2020 02:57:29
User entered '01 Dec 2020' reason for change: Per Query Resolution	(b) (4) Frances Saubon (b) (4)	18 Dec 2020 02:57:29
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4)	02 Nov 2020 22:09:27



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:19:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	02 Nov 2020 22:09:27

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User entered '3'	System	02 Nov 2020 22:09:27

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User entered '1'	System	02 Nov 2020 22:09:27

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:48
User entered '804 (804)'	System	02 Nov 2020 22:09:27

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 17:09:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Nov 2020 17:09:45
Data point term sent to Coder	System	16 Nov 2020 16:08:03
Data point term sent to Coder	System	16 Nov 2020 15:50:33
User entered 'Guaifenesin'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:19:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:19:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	Frances Saubon (b) (4)	16 Nov 2020 16:07:41
User entered 'Confirmed Covid-19'	Elisa Moralez (b) (4)	16 Nov 2020 15:49:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:19:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '600'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:59



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:19:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:19:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:19:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'once daily (QD)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:19:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered empty.	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:19:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:20:57
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 06 NOV 2020. '(Site from DM).		05 Jan 2021 01:22:07
DataPoint Un-verified.	Frances Saubon (b) (4)	21 Dec 2020 16:34:06
User entered '07 Nov 2020' reason for change: Per Query Resolution	(b) (4) Frances Saubon (b) (4)	21 Dec 2020 16:34:06
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 06 NOV 2020.	(b) (4) Elisa Moralez (b) (4)	14 Dec 2020 15:42:35
' answered with 'CM was given on 6 nov 2020' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding AE. Please review and reconcile the Con Med and AE start dates if applicable. Else, confirm CM was given on 06 NOV 2020. '(Site from DM).	(b) (4), (b) (6)	14 Dec 2020 05:00:54
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '06 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '0'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:59



**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:19:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered '12 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:19:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:25:55
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	16 Nov 2020 15:49:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User entered '1'	System	16 Nov 2020 15:49:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:19:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User entered '1'	System	16 Nov 2020 15:49:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:26:39
User entered '804 (804)'	System	16 Nov 2020 15:49:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
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)	08 Mar 2021 22:41:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 22:41:42
Data point term sent to Coder Coding entries removed.	System Elisa Moralez (b) (4)	08 Mar 2021 22:40:32 08 Mar 2021 22:40:23
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)	07 Mar 2021 00:46:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Mar 2021 00:46:09
Data point term sent to Coder User entered 'Ibuprofen'	System Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:32:47 04 Mar 2021 17:32:17

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:19:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'No (N)'	Elisa Moralez (b) (4)	04 Mar 2021 17:32:17



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:19:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'HEADACHES' reason for change:	(b) (4)	
Data Entry Error	Elisa Moralez (b) (4)	08 Mar 2021 22:40:23
User entered 'Headaches from eye strain'	(b) (4)	
	Elisa Moralez (b) (4)	04 Mar 2021 17:32:17
	(b) (4)	

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:19:05**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '400'	Elisa Moralez (b) (4)	04 Mar 2021 17:32:17

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:19:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'mg (mg)'	Elisa Moralez (b) (4)	04 Mar 2021 17:32:17

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:19:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	Elisa Moralez (b) (4)	04 Mar 2021 17:32:17

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:19:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'once daily (QD)'	Elisa Moralez (b) (4)	04 Mar 2021 17:32:17

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	Elisa Moralez (b) (4)	04 Mar 2021 17:32:17

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4)	04 Mar 2021 17:32:17

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:19:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	Elisa Moralez (b) (4)	04 Mar 2021 17:32:17



**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '15 Nov 2020'	Elisa Moralez (b) (4)	04 Mar 2021 17:32:17

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '0'	Elisa Moralez (b) (4)	04 Mar 2021 17:32:17

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:19:05**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	04 Mar 2021 17:32:17

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	Elisa Moralez (b) (4)	04 Mar 2021 17:32:17

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:19:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'No (N)'	Elisa Moralez (b) (4)	04 Mar 2021 17:32:17

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:32:17

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Mar 2021 17:32:17

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Mar 2021 17:32:17



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.	(b) (4)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 17:35:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 17:35:04
Data point term sent to Coder	System	04 Mar 2021 17:33:50
User entered 'Prednisone'	Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:19:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:19:05**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Tennis elbow'	(b) (4) Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:19:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '20'	(b) (4) Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:19:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'mg (mg)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:19:05**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:19:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'twice daily (BID)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03



**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'Oral (ORAL)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:19:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '09 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:19:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:19:05**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '15 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:19:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
DataPoint Verified.		13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 17:33:03

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
User entered '2'	System	04 Mar 2021 17:33:03



US3322409

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
User entered '1'	System	04 Mar 2021 17:33:03

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:51
User entered '804 (804)'	System	04 Mar 2021 17:33:03

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTS YNOM: MULTIVITAMINS [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Mar 2021 11:24:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	26 Mar 2021 11:24:42
Data point term sent to Coder	System	25 Mar 2021 14:11:18
User entered 'Prenatal multivitamins'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:19:05

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:34:32
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:48:36
DataPoint Verified.		13 Apr 2021 16:46:48
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).		06 Apr 2021 16:23:14
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4)	05 Apr 2021 18:27:05
Signature has been broken.	Elisa Moralez (b) (4)	05 Apr 2021 18:27:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	05 Apr 2021 18:27:00
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 16:55:07
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:19:05**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered 'Pregnancy'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:19:05

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered 'I'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:19:05**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered 'tablet (TABLET)'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:19:05

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered empty.	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:19:05

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered 'once daily (QD)'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered empty.	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:19:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered empty.	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered '26 Feb 2021'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered '0'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:19:05**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered empty.	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15



**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:19:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:15

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 14:11:15

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 14:11:15

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Mar 2021 14:11:15

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: OTHER DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, PRODUCT: SIMETICONE, PRODUCTS YNOMY: GAS-X - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:15:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:15:42
Data point term sent to Coder	System	07 Apr 2021 13:15:28
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
Data point term sent to Coder	System	26 Mar 2021 21:00:17
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
Data point term sent to Coder	System	25 Mar 2021 14:12:19
User entered 'Simethicone (Gas-X)'	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered 'Pregnancy'	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered '2'	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered 'tablet (TABLET)'	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered 'as needed (PRN)'	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered '08 Mar 2021'	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered '0'	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered empty.	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered empty.	System	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered empty.	System	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:19:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Elisa Moralez (b) (4) (b) (4)	07 Apr 2021 13:14:39
DataPoint inactivated with code reason code Data not required.	Moez Talpur (b) (4) (b) (4)	26 Mar 2021 20:59:50
User entered empty.	System	25 Mar 2021 14:11:39

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:19:05

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFTRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 06:50:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Mar 2021 06:50:19
Data point term sent to Coder	System	25 Mar 2021 14:12:20
User entered 'Ondansetron (Zofran)'	Elisa Morales (b) (4)	25 Mar 2021 14:11:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:19:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:59



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:19:05

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).		06 Apr 2021 16:24:23
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'due to pregnancy' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	05 Apr 2021 18:27:23
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 16:55:44
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	01 Apr 2021 00:02:09
User entered 'Nausea/vomiting'	Elisa Moralez (b) (4) (b) (4)	25 Mar 2021 14:11:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:19:05**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered '4'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:19:05

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered 'mg (mg)'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:19:05**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered empty.	Elisa Moralez (b) (4)	25 Mar 2021 14:11:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:19:05**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered 'as needed (PRN)'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:19:05

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered empty.	Elisa Moralez (b) (4)	25 Mar 2021 14:11:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:19:05**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:19:05

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered empty.	Elisa Moralez (b) (4)	25 Mar 2021 14:11:59



**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered '14 Mar 2021'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:19:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered '0'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:19:05**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:19:05**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered empty.	Elisa Moralez (b) (4)	25 Mar 2021 14:11:59

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:19:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:46:48
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:02:09
User entered 'No (N)'	Elisa Moralez (b) (4)	25 Mar 2021 14:11:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 14:11:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 14:11:59

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Mar 2021 14:11:59



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:19:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:57:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:57:44
Data point term sent to Coder	System	09 Apr 2021 16:54:29
User entered 'acetaminophen'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:19:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:19:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'abdominal cramps (pregnancy)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:19:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered '500'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:19:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'mg (mg)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:19:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:19:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'as needed (PRN)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47



US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:19:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'Oral (ORAL)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47

US3322409

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Aug 2021 22:19:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:19:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered '18 Feb 2021'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:19:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered '0'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Aug 2021 22:19:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:19:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47

US3322409

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Aug 2021 22:19:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:53:47

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:53:47



**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:53:47

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:53:47

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:19:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: DIPHTHERIA TETANUS PERTUSSIS VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:00:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 08:00:58
Data point term sent to Coder	System	09 Apr 2021 16:54:30
User entered 'Tetanus, Diphtheria, Pertussis vaccine'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:19:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:19:05**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'preventative healthcare'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:19:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'I'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:19:05**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'Other (OTHER)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:19:05**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'injection'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13



**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:19:05**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'once (ONCE)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:19:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:19:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'Intramuscular (INTRAMUSCULAR)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13

US3322409

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:19:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered empty.	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered '23 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:19:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered '0'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:19:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:19:05**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered '23 Oct 2020'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13



**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:19:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User signature succeeded.	Veronica Fragoso (b) (4)	15 Apr 2021 19:34:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:46:48
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	09 Apr 2021 16:54:13

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:19:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User entered empty.	System	09 Apr 2021 16:54:13

US3322409

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User entered empty.	System	09 Apr 2021 16:54:13

**US3322409**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Aug 2021 22:19:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:39:55
User entered empty.	System	09 Apr 2021 16:54:13

US3322409

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:19:05

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:49:57
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
User entered 'No (N)'	Elisa Moralez (b) (4)	20 Feb 2021 20:02:30

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'USA-US060-2020-MRNA-1273-P301000011'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38



**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (u) (*), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Veronica'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Teresa'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Veronica'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Fragoso'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Becker'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Fragoso'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '6550 Mapleridge Street'	System	17 Nov 2020 14:48:38



**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Houston'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'TX'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered empty.	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'TX'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '77081'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:27:46
DataPoint Verified.		20 Nov 2020 18:16:56
User entered 'US'	System	17 Nov 2020 14:49:09

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
	(b) (4)	
User entered '6'	System	12 Jan 2021 14:38:33
User entered '5'	System	30 Dec 2020 22:21:33
User entered '4'	System	22 Dec 2020 17:38:12
User entered '3'	System	21 Dec 2020 20:13:09
User entered '2'	System	30 Nov 2020 23:27:59
User entered '1'	System	17 Nov 2020 14:49:09

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'USA-US060-2020-MRNA-1273-P301000011'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38



**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Veronica'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Teresa'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Veronica'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	System	19 Mar 2021 20:32:52
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Fragoso'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Becker'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Fragoso'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '6550 Mapleridge Street'	System	17 Nov 2020 14:48:38



**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Houston'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	System	19 Mar 2021 20:32:52
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'TX'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered empty.	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'TX'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '77081'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:27:46
DataPoint Verified.		20 Nov 2020 18:16:56
User entered 'US'	System	17 Nov 2020 14:49:09

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
	(b) (4)	
User entered '6'	System	12 Jan 2021 14:38:33
User entered '5'	System	30 Dec 2020 22:21:33
User entered '4'	System	22 Dec 2020 17:38:12
User entered '3'	System	21 Dec 2020 20:13:09
User entered '2'	System	30 Nov 2020 23:27:59
User entered '1'	System	17 Nov 2020 14:49:09

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (1)**

**Generated On: 11 Aug 2021 22:19:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
User entered '17/Nov/2020 14:49'	System	17 Nov 2020 14:49:09

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:19:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:27:46
DataPoint Verified.		20 Nov 2020 18:16:56
User entered 'I'		17 Nov 2020 14:49:09

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'USA-US060-2020-MRNA-1273-P301000011'	System	17 Nov 2020 14:48:38



**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Veronica'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Teresa'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Veronica'	System	17 Nov 2020 14:48:38



US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	System	19 Mar 2021 20:32:52
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Fragoso'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Becker'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Fragoso'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '6550 Mapleridge Street'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Houston'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'TX'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered empty.	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'TX'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '77081'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:27:46
DataPoint Verified.		20 Nov 2020 18:16:56
User entered 'US'	System	17 Nov 2020 14:49:09

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
	(b) (4)	
User entered '6'	System	12 Jan 2021 14:38:33
User entered '5'	System	30 Dec 2020 22:21:33
User entered '4'	System	22 Dec 2020 17:38:12
User entered '3'	System	21 Dec 2020 20:13:09
User entered '2'	System	30 Nov 2020 23:27:59
User entered '1'	System	17 Nov 2020 14:49:09

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (2)**

**Generated On: 11 Aug 2021 22:19:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:01:24
User entered '30/Nov/2020 18:27'	System	30 Nov 2020 23:27:59



US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:19:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
User entered 'I'		30 Nov 2020 23:27:59

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'USA-US060-2020-MRNA-1273-P301000011'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38



**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Veronica'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Teresa'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Veronica'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Fragoso'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Becker'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Fragoso'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '6550 Mapleridge Street'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Houston'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	System	19 Mar 2021 20:32:52
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'TX'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered empty.	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'TX'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '77081'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:27:46
DataPoint Verified.		20 Nov 2020 18:16:56
User entered 'US'	System	17 Nov 2020 14:49:09



US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
	(b) (4)	
User entered '6'	System	12 Jan 2021 14:38:33
User entered '5'	System	30 Dec 2020 22:21:33
User entered '4'	System	22 Dec 2020 17:38:12
User entered '3'	System	21 Dec 2020 20:13:09
User entered '2'	System	30 Nov 2020 23:27:59
User entered '1'	System	17 Nov 2020 14:49:09

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (3)**

**Generated On: 11 Aug 2021 22:19:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:01:24
User entered '21/Dec/2020 15:13'	System	21 Dec 2020 20:13:09

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:19:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		21 Dec 2020 20:13:13
User entered 'I'		21 Dec 2020 20:13:09

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'USA-US060-2020-MRNA-1273-P301000011'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38



**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Veronica'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Teresa'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Veronica'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Fragoso'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Becker'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Fragoso'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '6550 Mapleridge Street'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Houston'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	System	19 Mar 2021 20:32:52
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'TX'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered empty.	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'TX'	System	17 Nov 2020 14:48:38



**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '77081'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	30 Nov 2020 23:27:46
DataPoint Verified.		20 Nov 2020 18:16:56
User entered 'US'	System	17 Nov 2020 14:49:09

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
	(b) (4)	
User entered '6'	System	12 Jan 2021 14:38:33
User entered '5'	System	30 Dec 2020 22:21:33
User entered '4'	System	22 Dec 2020 17:38:12
User entered '3'	System	21 Dec 2020 20:13:09
User entered '2'	System	30 Nov 2020 23:27:59
User entered '1'	System	17 Nov 2020 14:49:09

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (4)**

**Generated On: 11 Aug 2021 22:19:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:01:24
User entered '22/Dec/2020 17:38'	System	22 Dec 2020 17:38:12

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:19:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		30 Dec 2020 22:21:23
User entered 'I'		22 Dec 2020 17:38:12

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'USA-US060-2020-MRNA-1273-P301000011'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38



**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Veronica'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Teresa'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Veronica'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Fragoso'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Becker'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Fragoso'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '6550 Mapleridge Street'	System	17 Nov 2020 14:48:38



**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Houston'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	System	19 Mar 2021 20:32:52
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'TX'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered empty.	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'TX'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '77081'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:27:46
DataPoint Verified.		20 Nov 2020 18:16:56
User entered 'US'	System	17 Nov 2020 14:49:09

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
	(b) (4)	
User entered '6'	System	12 Jan 2021 14:38:33
User entered '5'	System	30 Dec 2020 22:21:33
User entered '4'	System	22 Dec 2020 17:38:12
User entered '3'	System	21 Dec 2020 20:13:09
User entered '2'	System	30 Nov 2020 23:27:59
User entered '1'	System	17 Nov 2020 14:49:09

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (5)**

**Generated On: 11 Aug 2021 22:19:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:01:24
User entered '30/Dec/2020 17:21'	System	30 Dec 2020 22:21:33

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:19:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		30 Dec 2020 22:21:36
User entered 'I'		30 Dec 2020 22:21:33

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'USA-US060-2020-MRNA-1273-P301000011'	System	17 Nov 2020 14:48:38



**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Veronica'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Teresa'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Veronica'	System	17 Nov 2020 14:48:38



US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	System	19 Mar 2021 20:32:52
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Fragoso'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Becker'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Fragoso'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '6550 Mapleridge Street'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Houston'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'TX'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered empty.	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'TX'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '77081'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:27:46
DataPoint Verified.		20 Nov 2020 18:16:56
User entered 'US'	System	17 Nov 2020 14:49:09

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
	(b) (4)	
User entered '6'	System	12 Jan 2021 14:38:33
User entered '5'	System	30 Dec 2020 22:21:33
User entered '4'	System	22 Dec 2020 17:38:12
User entered '3'	System	21 Dec 2020 20:13:09
User entered '2'	System	30 Nov 2020 23:27:59
User entered '1'	System	17 Nov 2020 14:49:09

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (6)**

**Generated On: 11 Aug 2021 22:19:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:01:24
User entered '12/Jan/2021 09:38'	System	12 Jan 2021 14:38:33



US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form (6)

Generated On: 11 Aug 2021 22:19:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Mar 2021 20:32:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 22:01:24
User entered 'I'		12 Jan 2021 14:38:33

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'USA-US060-2020-MRNA-1273-P301000011'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38



**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'No (N)'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Veronica'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Teresa'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Veronica'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'Fragoso'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered 'Becker'	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Fragoso'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '6550 Mapleridge Street'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'Houston'	System	17 Nov 2020 14:48:38

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	19 Mar 2021 20:32:52
Signature has been broken.	System	19 Mar 2021 20:32:52
User entered 'TX'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 22:01:24
Reviewed for Safety.		22 Dec 2020 17:37:59
Un-reviewed for Safety.	System	21 Dec 2020 20:13:09
DataPoint Un-verified.	System	21 Dec 2020 20:13:09
User entered empty.	System	21 Dec 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered 'TX'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 18:16:56
Reviewed for Safety.		17 Nov 2020 14:49:00
User entered '77081'	System	17 Nov 2020 14:48:38

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 11 Aug 2021 22:19:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:27:46
DataPoint Verified.		20 Nov 2020 18:16:56
User entered 'US'	System	17 Nov 2020 14:49:09



US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 11 Aug 2021 22:19:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	19 Mar 2021 20:32:52
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:13:04
	(b) (4)	
User entered '6'	System	12 Jan 2021 14:38:33
User entered '5'	System	30 Dec 2020 22:21:33
User entered '4'	System	22 Dec 2020 17:38:12
User entered '3'	System	21 Dec 2020 20:13:09
User entered '2'	System	30 Nov 2020 23:27:59
User entered '1'	System	17 Nov 2020 14:49:09

**US3322409**

**Folder: SAE USA-US060-2020-MRNA-1273-P301000011**

**Form: Safety Report Form (7)**

**Generated On: 11 Aug 2021 22:19:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered '19/Mar/2021 15:32'	(b) (4) System	19 Mar 2021 20:32:52

US3322409

Folder: SAE USA-US060-2020-MRNA-1273-P301000011

Form: Safety Report Form (7)

Generated On: 11 Aug 2021 22:19:05

**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)	09 Apr 2021 15:13:10
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:12:52
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 20:32:52