

US3522200 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:56:11

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US3522200

Form: Participant Creation

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

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Participant ID

US3522200

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

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US3522200

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3522200

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	29
Age Units	YEARS
Age (Derived)	29
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3522200

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Date of Informed Consent ( <i>dd MMM yyyy</i> )	19 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3522200

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 15:37:49

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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) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

Condition	ADJUSTMENT DISORDER WITH ANXIETY
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	



US3522200

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3522200

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	19 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	7:37 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 7:37
Height ( <i>xxx.x</i> )	67 in
Weight ( <i>xxx.x</i> )	144 lb
BMI ( <i>xxx.x</i> )	22.60075 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) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Date of assessment (*dd MMM yyyy*) 19 AUG 2020

Is the participant of childbearing potential? Yes ☒  
No ☐

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

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

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

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Was the pregnancy test performed? Yes ☒  
No ☐

Date of test (dd MMM yyyy) 19 AUG 2020

Test performed Urine ☒  
Serum ☐

Result Positive ☐  
Negative ☒

Was FSH sample collected? Yes ☐  
No ☒

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

US3522200

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 15:37:49

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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**

BANKER FOR (b) (6)

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 15:37:49

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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)	True
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

What was the date of randomization? (dd MMM yyyy) 19 AUG 2020

What was the participant's randomization number? 105602

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

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) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

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)	19 AUG 2020
Time of assessment (00:00-23:59)	7:55 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 7:55
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

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)	19 AUG 2020
Time of assessment (00:00-23:59)	10:06 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 10:06
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	54 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

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) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

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) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

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) 19 AUG 2020

What was the treatment time? (00:00-23:59) 09:36 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 09:36

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) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 AUG 2020
Collection time (00:00-23:59)	8:35 (24 HR)
Collection date and time (derived)	19 AUG 2020 8:35



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Collection date (dd MMM yyyy)			19 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	8:40	19 AUG 2020 8:40
Nasopharyngeal Swab 2	No		

US3522200

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 10:05

PC Open Date & Time

19 AUG 2020 09:56

PC Close Date & Time

19 AUG 2020 12:26

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 19 AUG 2020 19:00

PC Open Date & Time 19 AUG 2020 13:21

PC Close Date & Time 20 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**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

97.8 °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

20 AUG 2020 18:45

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 21:22

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**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

23 AUG 2020 09:42

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 06:49

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:11

**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

98.8 °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

25 AUG 2020 08:56

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

26 AUG 2020 07:09

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**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

19 AUG 2020 10:06

PC Open Date & Time

19 AUG 2020 09:56

PC Close Date & Time

19 AUG 2020 12:26

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**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

19 AUG 2020 19:03

PC Open Date & Time

19 AUG 2020 13:21

PC Close Date & Time

20 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 18:46

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**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

21 AUG 2020 21:22

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**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

23 AUG 2020 09:38

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**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

24 AUG 2020 06:49

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59



US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:11

**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

25 AUG 2020 08:57

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 07:09

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**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 ☐

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 10:07
PC Open Date & Time	19 AUG 2020 09:56
PC Close Date & Time	19 AUG 2020 12:26

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**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 ☐

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

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

No ☒

Yes ☐

PC Time stamp	19 AUG 2020 19:03
PC Open Date & Time	19 AUG 2020 13:21
PC Close Date & Time	20 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**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 ☒

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 18:46
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59



US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

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

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

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 ☒

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 09:38
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:11

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:11

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 06:50
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:11

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 ☒

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EAB) (1725)

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:11

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 08:57
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59



US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:11

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 ☒

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:11

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 07:10
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3522200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

ALEVE TAKEN AT HOME THE  
DAY OF INJECTION FOR PAIN  
IN BOTH ARMS FROM BLOOD  
DRAW AND INJECTION AND  
ALSO EXPERIENCED SOME  
FATIGUE THE SAME DAY;  
BOTH AE RESOLVED BY THE  
NEXT DAY.

US3522200

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 SEP 2020

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

Comments  
*If Contact Not Made, please provide Comments*  
NO ONGOING OR NEW AE  
REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE OR PREGNANCY  
RISK

US3522200

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 SEP 2020

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

Comments  
*If Contact Not Made, please provide Comments*  
NO ONGOING OR NEW AE  
REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE OR PREGNANCY  
RISK

US3522200

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3522200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:16:52

Generated On: 10 Jun 2021 07:56:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:16:52

Generated On: 10 Jun 2021 07:56:11

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 SEP 2020
Time of assessment (00:00-23:59)	13:45 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 13:45
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:16:52

Generated On: 10 Jun 2021 07:56:11

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 SEP 2020
Time of assessment (00:00-23:59)	14:45 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 14:45
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3522200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3522200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

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

US3522200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 18 SEP 2020

What was the treatment time? (00:00-23:59) 13:50 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 13:50

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

US3522200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 SEP 2020

Collection time (00:00-23:59)

13:58 (24 HR)

Collection date and time (derived)

18 SEP 2020 13:58

US3522200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:02	18 SEP 2020 14:02
Nasopharyngeal Swab 2	No		



US3522200

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 14:46

PC Open Date & Time

18 SEP 2020 14:10

PC Close Date & Time

18 SEP 2020 16:40

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**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 98.8 °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	19 SEP 2020 10:10
PC Open Date & Time	18 SEP 2020 17:35
PC Close Date & Time	19 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 11:33

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:11

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

97.9 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

21 SEP 2020 07:43

---

PC Open Date & Time

20 SEP 2020 12:00

---

PC Close Date & Time

21 SEP 2020 11:59

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US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**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

99.0 °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

22 SEP 2020 08:59

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 07:16

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:11

**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

98.8 °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

24 SEP 2020 09:06

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59



US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:11

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**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.

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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

99.2 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

25 SEP 2020 09:55

---

PC Open Date & Time

24 SEP 2020 12:00

---

PC Close Date & Time

25 SEP 2020 11:59

---

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 14:47

PC Open Date & Time

18 SEP 2020 14:10

PC Close Date & Time

18 SEP 2020 16:40

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**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

19 SEP 2020 10:10

PC Open Date & Time

18 SEP 2020 17:35

PC Close Date & Time

19 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 11:32

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**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

21 SEP 2020 07:43

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**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

22 SEP 2020 08:58

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**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

23 SEP 2020 07:15

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:11

**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

24 SEP 2020 09:06

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59



US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 09:55

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**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 ☐

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 14:47
PC Open Date & Time	18 SEP 2020 14:10
PC Close Date & Time	18 SEP 2020 16:40

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**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 ☐

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

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

No ☒

Yes ☐

PC Time stamp	19 SEP 2020 10:11
PC Open Date & Time	18 SEP 2020 17:35
PC Close Date & Time	19 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 11:33
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

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

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EAB) (1725)



US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 07:43
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

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 ☒

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 08:58
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:11

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:11

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 07:15
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:11

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:11

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 09:06
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:11

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 ☒



US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:11

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 09:55
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3522200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments  
*If Contact Not Made, please provide Comments*  
NO ONGOING OR NEW AE  
REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE OR PREGNANCY  
RISK.

US3522200

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments NO ONGOING AE REPORTED,  
NO NEW ILLNESS; NO  
If Contact Not Made, please provide Comments CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE OR PREGNANCY  
RISK. RECEIVING FLU VACCINE  
TODAY.

US3522200

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

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*  
NO ONGOING OR NEW AE  
REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE OR PREGNANCY  
RISK

US3522200

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:16:50

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:16:53

Generated On: 10 Jun 2021 07:56:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3



US3522200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 18:16:53

Generated On: 10 Jun 2021 07:56:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	08:40 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 08:40
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522200

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:16:53

Generated On: 10 Jun 2021 07:56:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

US3522200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:16:53

Generated On: 10 Jun 2021 07:56:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

08:45 (24 HR)

Collection date and time (derived)

23 OCT 2020 08:45

US3522200

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:16:53

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 OCT 2020 18:02:25

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3522200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 12:10:56

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3522200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 12:00:44

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3522200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 12:06:47

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59



US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 09:56:09
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 09:14:32

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	04 DEC 2020 14:18:57
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 10:04:41

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 13:29:36
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 09:10:41

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 00:01:42

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 12:04:14
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59



US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 17:59:27
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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

24 JAN 2021 12:03:51

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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

01 FEB 2021 06:54:18

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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

05 FEB 2021 08:07:41

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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

14 FEB 2021 12:22:22

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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

19 FEB 2021 06:53:47

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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

26 FEB 2021 20:09:01

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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

07 MAR 2021 12:22:11

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59



US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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

12 MAR 2021 12:07:46

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 08:40:31

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 09:35:26

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 06:16:46

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 13:08:40

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 APR 2021 12:00:41

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 12:02:07

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 06:06:09

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59



US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

---

18 MAY 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59



US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 JUL 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUL 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

TIMEPOINT	DAY 341
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59



US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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"/>

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 AUG 2021 23:59
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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 SEP 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

10 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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="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"/>

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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"/>

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59



US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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29 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 NOV 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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"/>

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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°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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 NOV 2021 23:59



US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Close Date & Time](#)

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07 DEC 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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



US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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"/>

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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17 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 DEC 2021 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐  
Yes ☐

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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07 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 JAN 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Close Date & Time](#)

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18 JAN 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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21 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JAN 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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22 FEB 2022 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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°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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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01 MAR 2022 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAR 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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"/>

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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08 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 APR 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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15 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 APR 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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22 APR 2022 00:01

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26 APR 2022 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59



US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Close Date & Time](#)

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14 JUN 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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°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"/>

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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17 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59



US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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12 JUL 2022 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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"/>

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Close Date & Time](#)

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19 JUL 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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



US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 719

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Close Date & Time](#)

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16 AUG 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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[Patient Cloud Open Date & Time](#)

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19 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 AUG 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 AUG 2022 00:01
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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐  
Yes ☐

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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16 SEP 2022 00:01

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20 SEP 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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[Patient Cloud Open Date & Time](#)

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23 SEP 2022 00:01

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27 SEP 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

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04 OCT 2022 23:59

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**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 ☐

**US3522200**

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

**Form: Safety Follow Up Diary**

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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07 OCT 2022 00:01

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11 OCT 2022 23:59

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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2022 23:59
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US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2022 23:59
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US3522200

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 07:56:11

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		07 MAR 2021 12:22:19

US3522200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

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

Comments  
*If Contact Not Made, please provide Comments*  
NO ONGOING OR NEW AE  
REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE OR PREGNANCY  
RISK.

US3522200

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

PAPILLARY THYROID IS STAGE  
1 AND WILL SEE SPECIALIST AT  
END OF DECEMBER 2020 IN  
PREPARATION FOR SURGERY.  
ON 05 DEC 2020, TOPIRAMATE  
WAS STOPPED AND SWITCHED  
TO PROPRANOLOL. NO  
COVID-19 EXPOSURE

US3522200

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 JAN 2021

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

Comments "NO ONGOING OR NEW AE  
If Contact Not Made, please provide Comments REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE OR PREGNANCY  
RISK."



US3522200

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

POST TOTAL  
THYROIDECTOMY, SHE  
UNDERWENT RADIOACTIVE  
IODINE TREATMENT FOR TALL  
CELL VARIANT PAPILLARY  
THYROID CANCER;  
LIOTHYRONINE WAS  
INCREASED FROM 50 25  
MICROGRAM TO 100  
MICROGRAMS ON 13 FEB 2021.

US3522200

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 11:34:28

Generated On: 10 Jun 2021 07:56:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3522200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 11:34:28

Generated On: 10 Jun 2021 07:56:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 MAR 2021
Time of assessment (00:00-23:59)	10:50 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 10:50
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522200

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 11:34:28

Generated On: 10 Jun 2021 07:56:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3522200

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 11:34:28

Generated On: 10 Jun 2021 07:56:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 MAR 2021

Collection time (00:00-23:59)

10:58 (24 HR)

Collection date and time (derived)

26 MAR 2021 10:58

US3522200

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 11:34:28

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3522200

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 19:01:47

Generated On: 10 Jun 2021 07:56:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 APR 2021

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

Comments  
*If Contact Not Made, please provide Comments*

NO ONGOING OR NEW AE  
REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE OR PREGNANCY  
RISK.

US3522200

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 19:01:47

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3522200**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

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*

**US3522200**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3522200

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:56:11

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

**US3522200**

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

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

**Generated On: 10 Jun 2021 07:56:11**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3522200

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

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

Visit date (dd MMM yyyy)	22 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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US3522200

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 18:07:46

Generated On: 10 Jun 2021 07:56:11

Date of updated informed consent ( <i>dd MMM yyyy</i> )	22 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> )	22 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



US3522200

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Height	67 in
Weight	135 lb
BMI (xxx.x)	21.18820

US3522200

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Height	67 in
Weight	135 lb
BMI (xxx.x)	21.18820
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)	22 JAN 2021
Time of assessment (00:00-23:59)	14:20 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 14:20
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3522200

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Height	67 in
Weight	135 lb
BMI (xxx.x)	21.18820
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)	22 JAN 2021
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 15:00
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3522200

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 JAN 2021

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

US3522200

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

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

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) \_\_\_\_\_

US3522200

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

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

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) 22 JAN 2021

What was the treatment time? (00:00-23:59) 14:22 (24 HR)

Treatment Date and Time (derived) 22 JAN 2021 14:22

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

US3522200

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

14:15 (24 HR)

Collection date and time (derived)

22 JAN 2021 14:15

US3522200

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	14:15
Collection Date and Time (derived)	22 JAN 2021 14:15



US3522200

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

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 JAN 2021

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

Comments NO ONGOING OR NEW AE  
REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE OR PREGNANCY  
RISK.

*If Contact Not Made, please provide Comments*

US3522200

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

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

US3522200

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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

US3522200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

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)	19 FEB 2021
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 11:50
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3522200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

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)	19 FEB 2021
Time of assessment (00:00-23:59)	12:28 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 12:28
Temperature (xxx.x)	99.3 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3522200

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 FEB 2021

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

US3522200

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	19 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)	



US3522200

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

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) 19 FEB 2021

What was the treatment time? (00:00-23:59) 11:58 (24 HR)

Treatment Date and Time (derived) 19 FEB 2021 11:58

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

US3522200

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 FEB 2021

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

Comments NO ONGOING OR NEW AE  
REPORTED, NO NEW ILLNESS  
OR HOSPITAL VISITS; NO  
CHANGES IN HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE OR PREGNANCY  
RISK.

*If Contact Not Made, please provide Comments*

US3522200

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3522200

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 11:34:28

Generated On: 10 Jun 2021 07:56:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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

US3522200

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 11:34:28

Generated On: 10 Jun 2021 07:56:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	26 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	10:50 (24 HR)
Vital Signs Date and Time (derived)	26 MAR 2021 10:50
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	72 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522200

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 11:34:28

Generated On: 10 Jun 2021 07:56:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 MAR 2021

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

US3522200

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 11:34:28

Generated On: 10 Jun 2021 07:56:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 MAR 2021

Collection time (00:00-23:59)

10:58 (24 HR)

Collection date and time (derived)

26 MAR 2021 10:58



US3522200

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3522200

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 18:07:46

Generated On: 10 Jun 2021 07:56:11

AEID	USA-US131-2020-MRNA-1273-P30 1000012
Adverse event	PAPILLARY THYROID CANCER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	1 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	True
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 18:07:46

Generated On: 10 Jun 2021 07:56:11

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	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3522200

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 19 Mar 2021 18:07:46

Generated On: 10 Jun 2021 07:56:11

---

PATIENT JUST DIAGNOSED.  
SHE WILL BE MEETING WITH A  
SURGEON IN THE FUTURE AND  
STARTING SOME  
MEDICATIONS.

17 DEC 2020 UPDATE:  
PAPILLARY THYROID CANCER  
IS STAGE 1 (WILL KEEP GRADE  
AS GRADE 2) AND SHE WILL BE  
SEEING A SPECIALIST AT THE  
END OF DECEMBER 2020 IN  
PREPARATION FOR SURGERY.  
ON 05 DEC 2020, TOPIRAMATE  
WAS STOPPED BECAUSE IT  
WAS INTERFERING WITH HER  
BIRTH CONTROL SO SHE WAS  
SWITCHED TO PROPRANOLOL  
40 MG TWICE DAILY ON 05 DEC  
2020.

HAD A TOTAL  
THYROIDECTOMY WITH RLN  
MONITORING, CENTRAL  
COMPARTMENT LYMPH NODE  
DISSECTION, LEFT MODIFIED  
RADICAL NECK DISSECTION  
LOGGED AS CONCOM.  
PROCEDURE

16 FEB 2021: POST TOTAL  
THYROIDECTOMY, SHE  
UNDERWENT RADIOACTIVE  
IODINE TREATMENT ON 11 FEB  
2021 FOR TALL CELL VARIANT  
PAPILLARY THYROID CANCER;  
LIOTHYRONINE WAS  
INCREASED FROM 50 25  
MICROGRAM TO 100  
MICROGRAMS ON 13 FEB 2021.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
--	---

Medically Attended AE Derived (CSA Programming Field Only)	1
--	---

---

Admitted to ICU Derived (CSA Programming Field Only)	
--	--

---

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EAB) (1725)

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

---

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

Yes ☒

No ☐

---

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

---

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

Name of Medication MICROGESTIN FE  
NORGESTIMATE/ETHINYL  
ESTRADIOL

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

Dose per administration 1.5/30

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

If dose unit is Other, specify MG/MCG

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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EAB) (1725)

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US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

	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)	UN APR 2019	
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"/>

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

Name of Medication ALEVE

Prophylaxis Yes ☐  
No ☒

Indication PAIN AT INJECTION/BLOOD  
DRAW SITE

Dose per administration 440

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 (2)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

	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 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 AUG 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) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication 14 DAYS POST 2ND IP

Dose per administration 1

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

If dose unit is Other, specify SHOT

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) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

	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)	2 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)		2 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"/>

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

Name of Medication PAXIL

Prophylaxis Yes ☐  
No ☒

Indication ADJUSTMENT DISORDER WITH ANXIETY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

	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 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"/>

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

Name of Medication TOPIRAMATE

Prophylaxis Yes ☐  
No ☒

Indication NOT CLEARLY KNOWN BY PARTICIPANT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

	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)	04 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	5 DEC 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"/>

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

Name of Medication PROPRANOLOL

Prophylaxis Yes ☐  
No ☒

Indication PAPILLARY THYROID CANCER

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

	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)		5 DEC 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

Name of Medication LIOTHYRONINE

Prophylaxis Yes ☐  
No ☒

Indication HYPO-THYROID

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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EAB) (1725)

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 FEB 2021		
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"/>

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

Name of Medication LIOTHYRONINE

Prophylaxis Yes ☐  
No ☒

Indication HYPOTHYROIDISM POST  
THYROIDECTOMY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Mar 2021 15:18:42

Generated On: 10 Jun 2021 07:56:11

	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)		13 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"/>

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Mar 2021 15:37:48

Generated On: 10 Jun 2021 07:56:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
24 NOV 2020	THYROID ULTRASOUND	Diagnostic	
24 NOV 2020	THYROID FNA BIOPSY	Diagnostic	
15 JAN 2021	THYROIDECTOMY	Adverse Event	
11 FEB 2021	RADIOACTIVE IODINE TREATMENT	Adverse Event	
16 FEB 2021	CENTRAL COMPARTMENT LYMPH NODE DISSECTION	Adverse Event	
16 FEB 2021	LEFT MODIFIED RADICAL NECK DISSECTION.	Adverse Event	

US3522200

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:56:11

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



US3522200

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:56:11

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 ☐

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

SAEID	USA-US131-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

SAEID	USA-US131-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	05/DEC/2020 18:42
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

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

SAEID	USA-US131-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	17/DEC/2020 15:14
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

SAEID	USA-US131-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	21/DEC/2020 13:30
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

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

SAEID	USA-US131-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/DEC/2020 12:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

SAEID	USA-US131-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	25/JAN/2021 13:17
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

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form (6)

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

SAEID	USA-US131-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	02/FEB/2021 12:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form (7)

Data signed: (b) (4) 05 Mar 2021 15:37:49

Generated On: 10 Jun 2021 07:56:11

SAEID	USA-US131-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	PAUL
Investigator's Last Name	KILGORE
Site Address: Street	(b) (6)
Site Address: City	(b) (6)
Site Address: State	MI
Site Address: Postal Code	(b) (6)
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	17/FEB/2021 11:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3522200 (Prod: Henry Ford Health System)

**US3522200**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 07:56:11**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'US3522200'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 11:39:29

**US3522200**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:36:38

US3522200

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 11:39:30

US3522200

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:36:38

**US3522200**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'SCRN'	System	19 Aug 2020 12:36:38

US3522200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered (b) (6) 1991'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 11:39:31



**US3522200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:11**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '29'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:46:26

**US3522200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:11**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'YEARS'	System	19 Aug 2020 11:46:26

**US3522200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:11**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered '29'	System	19 Aug 2020 11:47:25

**US3522200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:11**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:46:26

**US3522200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:11**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:46:26

**US3522200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:11**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:46:26

**US3522200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:11**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:46:26

**US3522200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:11**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:46:26



**US3522200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:11**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:46:26

**US3522200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:11**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:46:26

**US3522200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:11**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:46:26

US3522200

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:56:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:46:26

**US3522200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:11**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:46:26

**US3522200**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 07:56:11**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:46:26

US3522200

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:47:25

**US3522200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'Aug 2020'	System	19 Aug 2020 11:47:25



**US3522200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered '2020'	System	19 Aug 2020 11:47:25

**US3522200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:11**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:47:25

US3522200

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:47:25

**US3522200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:11**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:47:25

**US3522200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:11**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:47:25

**US3522200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:11**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:47:25

US3522200

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:56:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	19 Aug 2020 11:39:30

**US3522200**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 07:56:11**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'I'	System	19 Aug 2020 11:47:34



US3522200

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:47:34

US3522200

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:56:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4), (b) (6)	28 Dec 2020 13:15:00
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 11:47:41

US3522200

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:56:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User coded data point as SOC: Psychiatric disorders, HLGT: Adjustment disorders (incl subtypes), HLT: Adjustment disorders, PT: Adjustment disorder with anxiety, LLT: Adjustment disorder with anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 13:16:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Dec 2020 13:16:18
Data point term sent to Coder	System	28 Dec 2020 13:15:46
User entered 'adjustment disorder with anxiety'	(b) (4), (b) (6)	28 Dec 2020 13:15:23

**US3522200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 13:15:23

**US3522200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 13:15:23

**US3522200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 13:15:23

**US3522200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 13:15:23

**US3522200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 13:15:23



**US3522200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered empty.	System	28 Dec 2020 13:15:23

**US3522200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered empty.	System	28 Dec 2020 13:15:23

**US3522200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered empty.	System	28 Dec 2020 13:15:23

**US3522200**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered empty.	System	28 Dec 2020 13:15:23

US3522200

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:56:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 19:28:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 19:28:39
Data point term sent to Coder	System	09 Mar 2021 19:28:16
User entered 'Hypothyroidism'	(b) (4), (b) (6)	09 Mar 2021 19:27:11

**US3522200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:27:11

**US3522200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:27:11

**US3522200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:27:11



**US3522200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:27:11

**US3522200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 19:27:11

**US3522200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered empty.	System	09 Mar 2021 19:27:11

**US3522200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered empty.	System	09 Mar 2021 19:27:11

**US3522200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered empty.	System	09 Mar 2021 19:27:11

**US3522200**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered empty.	System	09 Mar 2021 19:27:11

US3522200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:49:01

**US3522200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:49:01



US3522200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '7:37'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:49:01

**US3522200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered '19 Aug 2020 7:37'	System	19 Aug 2020 11:49:01

US3522200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '67' in	(b) (4), (b) (6)	19 Aug 2020 11:49:01
DataPoint set to visible.	System	19 Aug 2020 11:47:34

US3522200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '144' lb	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:49:01
DataPoint set to visible.	System	19 Aug 2020 11:47:34

US3522200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
Amendment Manager: User entered '22.60075'	System	17 Sep 2020 00:13:21
User entered '22.6'	System	19 Aug 2020 11:49:01
DataPoint set to visible.	System	19 Aug 2020 11:47:34

**US3522200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'kg/m2'	System	19 Aug 2020 11:49:01
DataPoint set to visible.	System	19 Aug 2020 11:47:34

US3522200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:49:01

US3522200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Aug 2020 15:26:29
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 14:31:28
Query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' answered with 'done' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	25 Aug 2020 14:31:14
User opened query 'Per CDM : 'ND' noted for Temperature; however please also keep the 'Route of measurement' blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 07:27:25
User entered 'Oral (Oral)'	(b) (4), (b) (6)	19 Aug 2020 11:49:01



US3522200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:49:01

**US3522200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:49:01

**US3522200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'bpm'	System	19 Aug 2020 11:49:01

US3522200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:49:01

**US3522200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'breaths/min'	System	19 Aug 2020 11:49:01

US3522200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:49:01

**US3522200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'mmHg'	System	19 Aug 2020 11:49:01

US3522200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:49:01



**US3522200**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'mmHg'	System	19 Aug 2020 11:49:01

US3522200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50

US3522200

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50

US3522200

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:49:14

**US3522200**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:11**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:49:14

US3522200

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:56:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:52:02

US3522200

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:56:11

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:52:02

US3522200

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:56:11

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:52:02



**US3522200**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:56:11**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:52:02

**US3522200**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:52:02

**US3522200**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 07:56:11**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:52:02

US3522200

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:52:02

US3522200

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:56:11

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:52:02

**US3522200**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:52:21

**US3522200**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:52:21

**US3522200**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:52:21



US3522200

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	19 Aug 2020 12:56:31
User entered 'Negative (NEGATIVE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 12:56:31
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 11:52:21
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:52:21

US3522200

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:11

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Per CDM: Was FSH sample collected? is No however collection date is provided. Please verify and update else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:38:22
Query 'Per CDM: Was FSH sample collected? is No however collection date is provided. Please verify and update else clarify.' answered with 'FSH sample not collected; collection date removed' (Site from DM).	Tyler Prentiss (b) (4) (b) (4)	01 Sep 2020 12:01:44
User opened query 'Per CDM: Was FSH sample collected? is No however collection date is provided. Please verify and update else clarify.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 10:35:29
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 12:56:31
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:52:21

US3522200

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty; reason for change Data Entry Error	(b) (4)	
	Tyler Prentiss (b) (4)	01 Sep 2020 12:01:16
	(b) (4)	
User entered '19 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 12:56:31
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:52:21

US3522200

Folder: Screening

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty; reason for change Data Entry Error	(b) (4)	01 Sep 2020 12:01:16
User entered '08:50' reason for change: Data Entry Error	Tyler Prentiss (b) (4)	19 Aug 2020 12:56:31
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:52:21

**US3522200**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered empty.	System	01 Sep 2020 12:01:16
User entered '19 Aug 2020 08:50'	System	19 Aug 2020 12:56:31
User entered empty.	System	19 Aug 2020 11:52:21

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

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 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Aug 2020 14:41:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 14:41:17
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:41:17
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 11:59:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

**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 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Aug 2020 14:41:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 14:41:17
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:41:17
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 11:59:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

**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 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Aug 2020 14:41:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 14:41:17
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:41:17
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 11:59:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:59:45



US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

**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 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	19 Aug 2020 14:41:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 14:41:17
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:41:17
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 11:59:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

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 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Aug 2020 14:41:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 14:41:17
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:41:17
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 11:59:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

[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 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Aug 2020 14:41:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 14:41:17
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:41:17
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 11:59:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

**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 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Aug 2020 14:41:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 14:41:17
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:41:17
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 11:59:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

**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 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Aug 2020 14:41:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 14:41:17
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:41:17
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 11:59:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

[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 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Aug 2020 14:41:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 14:41:17
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:41:17
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 11:59:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

**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 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Aug 2020 14:41:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 14:41:17
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:41:17
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 11:59:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

**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 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Aug 2020 14:41:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 14:41:17
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:41:17
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 11:59:45
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 11:59:45



**US3522200**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 07:56:11**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Banker for (b) (6) '	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:59:45

**US3522200**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 07:56:11**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

**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 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

[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 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

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 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'I'	(b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:59:45



**US3522200**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 07:56:11**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:59:45

US3522200

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:56:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 11:59:45

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:00:02

US3522200

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:00:02

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:00:02

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'VISIT1'	System	19 Aug 2020 12:00:02

US3522200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '19 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 11:44:28

US3522200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:28:44
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:28:44
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 11:44:28
User entered '105602' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 11:44:28



US3522200

Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 11:44:28

US3522200

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:56:11

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)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:20:32

US3522200

Folder: Visit 1 Day 1

Form: Randomization

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Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:20:32

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:20:32

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 07:56:11**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:20:32

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 07:56:11**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:20:32

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:40:44
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' answered with 'ok' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	02 Sep 2020 15:27:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	02 Sep 2020 15:27:24
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 17:23:56
User entered '67' in	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Sep 2020 15:27:32
User entered '144' lb	(b) (4), (b) (6)	19 Aug 2020 12:10:25



US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:40:44
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' answered with 'ok' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	02 Sep 2020 15:27:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	02 Sep 2020 15:27:24
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 17:23:56
User entered '67' in	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Sharon Mathys (b) (4)	02 Sep 2020 15:27:32
User entered '144' lb	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '7:55'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered '19 Aug 2020 7:55'	System	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '98.2' F	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:10:25



US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	02 Sep 2020 15:29:49
User entered 'IR'	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '73'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:10:25

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'bpm'	System	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '15'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'breaths/min'	System	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '131'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:10:25

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'mmHg'	System	19 Aug 2020 12:10:25



US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '75'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'mmHg'	System	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Sep 2020 17:40:44
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' answered with 'ok' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	02 Sep 2020 15:27:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Sharon Mathys (b) (4) (b) (4)	02 Sep 2020 15:27:24
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT on this form, as the screening and V1D1 has occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	27 Aug 2020 17:23:56
User entered '67' in	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:11

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Sep 2020 15:27:32
User entered '144' lb	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Aug 2020 14:46:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 14:46:13
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:46:13
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 12:10:25
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '19 Aug 2020' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:46:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 05:28:41
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minutes after injection' (Site from System).	(b) (4), (b) (6)	19 Aug 2020 18:34:49
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	19 Aug 2020 14:46:13
User entered '10:06' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:46:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:10:25



**US3522200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered '19 Aug 2020 10:06'	System	19 Aug 2020 14:46:13
User entered empty.	System	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '98.1' F reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:46:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Other (Other)' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:46:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Temporal' reason for change: New Information	(b) (4)	
	Sharon Mathys (b) (4)	02 Sep 2020 15:29:49
User entered 'IR' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:46:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '72' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:46:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:10:25

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'bpm'	System	19 Aug 2020 14:46:13
User entered empty.	System	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '16' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:46:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'breaths/min'	System	19 Aug 2020 14:46:13
User entered empty.	System	19 Aug 2020 12:10:25



US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '133' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:46:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'mmHg'	System	19 Aug 2020 14:46:13
User entered empty.	System	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 09:09:44
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Sharon Mathys (b) (4) (b) (4)	17 Sep 2020 13:53:32
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:13:21
User entered '54' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 14:46:13
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'mmHg'	System	19 Aug 2020 14:46:13
User entered empty.	System	19 Aug 2020 12:10:25

US3522200

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	02 Sep 2020 15:27:15
User entered 'Yes (Y)'	Sharon Mathys (b) (4)	19 Aug 2020 12:20:55
	(b) (4), (b) (6)	

US3522200

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered empty; reason for change Data Entry Error	Sharon Mathys (b) (4)	02 Sep 2020 15:27:15
User entered '19 Aug 2020'	(b) (4), (b) (6)	19 Aug 2020 12:20:55

US3522200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:11

Was the pregnancy test performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User closed query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Sep 2020 16:38:32
Query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' answered with 'done' (Site from DM).	Tyler Prentiss (b) (4) (b) (4)	01 Sep 2020 12:01:02
User entered 'No (N)' reason for change: Data Entry Error	Tyler Prentiss (b) (4) (b) (4)	01 Sep 2020 12:00:55
User opened query 'Per CDM: Screening and V1D1 have occurred on a same day and data reported on this page is matches at Pregnancy test form at Screening. Please consider to mark responses for Was the pregnancy test performed? and Was FSH sample collected? as No and make rest other data points at this page as blank. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:02:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 12:57:18

US3522200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered empty; reason for change Data Entry Error	(b) (4)	01 Sep 2020 12:00:55
User entered '19 Aug 2020'	Tyler Prentiss (b) (4)	19 Aug 2020 12:57:18
	(b) (4), (b) (6)	



US3522200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:11

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered empty; reason for change Data Entry Error	(b) (4)	01 Sep 2020 12:00:55
User entered 'Urine (URINE)'	Tyler Prentiss (b) (4)	19 Aug 2020 12:57:18
	(b) (4), (b) (6)	

US3522200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:11

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered empty; reason for change Data Entry Error	(b) (4)	01 Sep 2020 12:00:55
User entered 'Negative (NEGATIVE)'	Tyler Prentiss (b) (4)	19 Aug 2020 12:57:18
	(b) (4), (b) (6)	

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:57:18

US3522200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:11

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered empty; reason for change Data Entry Error	(b) (4)	01 Sep 2020 12:00:55
User entered '19 Aug 2020'	Tyler Prentiss (b) (4)	19 Aug 2020 12:57:18
	(b) (4), (b) (6)	

US3522200

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:11

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered empty; reason for change Data Entry Error	(b) (4)	01 Sep 2020 12:00:55
User entered '08:50'	Tyler Prentiss (b) (4)	19 Aug 2020 12:57:18
	(b) (4), (b) (6)	

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered empty.	System	01 Sep 2020 12:00:55
User entered '19 Aug 2020 08:50'	System	19 Aug 2020 12:57:18

US3522200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	(b) (4)	19 Aug 2020 13:42:36
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	19 Aug 2020 13:42:36
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	19 Aug 2020 12:21:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 12:21:37

US3522200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:21:37



US3522200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

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)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:21:37

US3522200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 12:21:37

US3522200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:21:37

US3522200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '09:36' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 13:39:34
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:21:37

US3522200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered '19 Aug 2020 09:36'	System	19 Aug 2020 13:39:34
User entered empty.	System	19 Aug 2020 12:21:37

US3522200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Left Arm (LEFT ARM)' reason for change: New Information	(b) (4)	19 Aug 2020 13:42:36
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:21:37

US3522200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'ONCE'	System	19 Aug 2020 12:21:37

US3522200

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 12:21:37



US3522200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:21:59

US3522200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:21:59

US3522200

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	19 Aug 2020 13:08:30
User entered '8:35' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 13:08:30
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 12:21:59
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:21:59

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered '19 Aug 2020 8:35'	System	19 Aug 2020 13:08:30
User entered empty.	System	19 Aug 2020 12:21:59

US3522200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:56:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '19 Aug 2020'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:22:14

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	19 Aug 2020 12:22:14

US3522200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:22:14

US3522200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '8:40' reason for change: New Information	(b) (4)	19 Aug 2020 13:08:17
User closed query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	19 Aug 2020 13:08:06
Query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' answered by data change (Site from System).	System	19 Aug 2020 13:08:06
User entered '8:45' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 13:08:06
User opened query "Was the sample collected?" is Yes, however, Collection Time is missing. Please review and reconcile.' (Site from System).	System	19 Aug 2020 12:22:14
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:22:14



**US3522200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered '19 Aug 2020 8:40'	System	19 Aug 2020 13:08:17
User entered '19 Aug 2020 8:45'	System	19 Aug 2020 13:08:06
User entered empty.	System	19 Aug 2020 12:22:14

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	19 Aug 2020 12:22:14

US3522200

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:56:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Aug 2020 12:22:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 12:22:20
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 12:22:20
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 12:22:14
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:22:14

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:22:14

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered empty.	System	19 Aug 2020 12:22:14

US3522200

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:56:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:22:38

**US3522200**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'I'	System	19 Aug 2020 12:22:38

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 13:39:34



US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:04:53', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '5d60ee6d-c34e-48b0-bbe2-9aa539c938c8' User entered 'Yes (Y)'	System	19 Aug 2020 14:05:44
	System	19 Aug 2020 14:05:44

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:05:30', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '5d60ee6d-c34e-48b0-bbe2-9aa539c938c8' User entered '98.1'	System	19 Aug 2020 14:05:44
	System	19 Aug 2020 14:05:44

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:05:36', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '5d60ee6d-c34e-48b0-bbe2-9aa539c938c8' User entered 'No (N)'	System	19 Aug 2020 14:05:44
	System	19 Aug 2020 14:05:44

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:05:42', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '5d60ee6d-c34e-48b0-bbe2-9aa539c938c8' User entered '19 Aug 2020 10:05'	System	19 Aug 2020 14:05:44
	System	19 Aug 2020 14:05:44

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Aug 2020 09:56'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Aug 2020 12:26'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:00:32', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '9b5fb1a5-212c-440a-b995-d57dde0bb511' User entered 'Yes (Y)'	System	19 Aug 2020 23:00:55
	System	19 Aug 2020 23:00:55



US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:00:37', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '9b5fb1a5-212c-440a-b995-d57dde0bb511' User entered '98.3'	System	19 Aug 2020 23:00:55
	System	19 Aug 2020 23:00:55

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:00:42', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '9b5fb1a5-212c-440a-b995-d57dde0bb511'	System	19 Aug 2020 23:00:55
User entered 'Yes (Y)'	System	19 Aug 2020 23:00:55

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
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 'took OTC Aleve once for pain at injection and blood draw site; see Line 2 in Concomitant Medications' (Site from System).	(b) (4), (b) (6)	26 Aug 2020 18:52:13
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).	Yaman Ahmed (b) (4)	26 Aug 2020 14:11:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:00:46', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '9b5fb1a5-212c-440a-b995-d57dde0bb511'	(b) (4)	
User entered '1'	System	19 Aug 2020 23:00:55
	System	19 Aug 2020 23:00:55
	System	19 Aug 2020 23:00:55

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:00:46', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '9b5fb1a5-212c-440a-b995-d57dde0bb511' User entered '0'	System	19 Aug 2020 23:00:55
	System	19 Aug 2020 23:00:55

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:00:52', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '9b5fb1a5-212c-440a-b995-d57dde0bb511'	System	19 Aug 2020 23:00:55
User entered '19 Aug 2020 19:00'	System	19 Aug 2020 23:00:55

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Aug 2020 13:21'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 2'	System	19 Aug 2020 13:39:34



US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:45:43', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '25f2f6ff-b166-4543-89a8-d10610d1fec1' User entered 'Yes (Y)'	System	20 Aug 2020 22:46:01
	System	20 Aug 2020 22:46:01

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:45:51', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '25f2f6ff-b166-4543-89a8-d10610d1fec1' User entered '97.8'	System	20 Aug 2020 22:46:01
	System	20 Aug 2020 22:46:01

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:45:56', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '25f2f6ff-b166-4543-89a8-d10610d1fec1'	System	20 Aug 2020 22:46:01
User entered 'No (N)'	System	20 Aug 2020 22:46:01

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:45:59', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '25f2f6ff-b166-4543-89a8-d10610d1fec1' User entered '20 Aug 2020 18:45'	System	20 Aug 2020 22:46:01
	System	20 Aug 2020 22:46:01

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 3'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:21:52', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '30df9f17-53b8-4aec-94ec-8cb6e5fd0560' User entered 'Yes (Y)'	System	22 Aug 2020 01:22:08
	System	22 Aug 2020 01:22:08



US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:21:56', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '30df9f17-53b8-4aec-94ec-8cb6e5fd0560' User entered '97.2'	System	22 Aug 2020 01:22:08
	System	22 Aug 2020 01:22:08

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:02', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '30df9f17-53b8-4aec-94ec-8cb6e5fd0560'	System	22 Aug 2020 01:22:08
User entered 'No (N)'	System	22 Aug 2020 01:22:08

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:06', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '30df9f17-53b8-4aec-94ec-8cb6e5fd0560' User entered '21 Aug 2020 21:22'	System	22 Aug 2020 01:22:08
	System	22 Aug 2020 01:22:08

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 4'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:42:01', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b1479c98-de8b-457e-b781-9a3e214b1a4f' User entered 'Yes (Y)'	System	23 Aug 2020 13:42:32
	System	23 Aug 2020 13:42:32

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:42:20', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b1479c98-de8b-457e-b781-9a3e214b1a4f' User entered '98.9'	System	23 Aug 2020 13:42:32
	System	23 Aug 2020 13:42:32



US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:42:28', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b1479c98-de8b-457e-b781-9a3e214b1a4f' User entered 'No (N)'	System	23 Aug 2020 13:42:32
	System	23 Aug 2020 13:42:32

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:42:30', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b1479c98-de8b-457e-b781-9a3e214b1a4f' User entered '23 Aug 2020 09:42'	System	23 Aug 2020 13:42:32
	System	23 Aug 2020 13:42:32

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 5'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:47:34', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '036ba320-a3cd-4920-aada-ba82955dec19' User entered 'Yes (Y)'	System	24 Aug 2020 10:49:40
	System	24 Aug 2020 10:49:40

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:49:23', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '036ba320-a3cd-4920-aada-ba82955dec19' User entered '98.6'	System	24 Aug 2020 10:49:40
	System	24 Aug 2020 10:49:40

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:49:34', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '036ba320-a3cd-4920-aada-ba82955dec19'	System	24 Aug 2020 10:49:40
User entered 'No (N)'	System	24 Aug 2020 10:49:40



**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:49:37', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '036ba320-a3cd-4920-aada-ba82955dec19' User entered '24 Aug 2020 06:49'	System	24 Aug 2020 10:49:40
	System	24 Aug 2020 10:49:40

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 6'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:54:58', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'c42dec47-07c5-4ced-a2a0-bf13f5aa6ca2' User entered 'Yes (Y)'	System	25 Aug 2020 12:56:43
	System	25 Aug 2020 12:56:43

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:56:33', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'c42dec47-07c5-4ced-a2a0-bf13f5aa6ca2' User entered '98.8'	System	25 Aug 2020 12:56:43
	System	25 Aug 2020 12:56:43

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:56:40', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'c42dec47-07c5-4ced-a2a0-bf13f5aa6ca2'	System	25 Aug 2020 12:56:43
User entered 'No (N)'	System	25 Aug 2020 12:56:43

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:56:42', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'c42dec47-07c5-4ced-a2a0-bf13f5aa6ca2' User entered '25 Aug 2020 08:56'	System	25 Aug 2020 12:56:43
	System	25 Aug 2020 12:56:43



**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 7'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:07:37', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'f429f89f-b7c2-45a3-95e3-acd238ffe98f' User entered 'Yes (Y)'	System	26 Aug 2020 11:09:48
	System	26 Aug 2020 11:09:48

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:09:30', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'f429f89f-b7c2-45a3-95e3-acd238ffe98f' User entered '98.4'	System	26 Aug 2020 11:09:48
	System	26 Aug 2020 11:09:48

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:09:43', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'f429f89f-b7c2-45a3-95e3-acd238ffe98f' User entered 'No (N)'	System	26 Aug 2020 11:09:48
	System	26 Aug 2020 11:09:48

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:09:45', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'f429f89f-b7c2-45a3-95e3-acd238ffe98f' User entered '26 Aug 2020 07:09'	System	26 Aug 2020 11:09:48
	System	26 Aug 2020 11:09:48

US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 13:39:34



US3522200

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:06:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '22caf863-2a94-4c9f-9e8c-8553906cb4ad'	System	19 Aug 2020 14:06:26
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 14:06:26

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:06:08', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '22caf863-2a94-4c9f-9e8c-8553906cb4ad'	System	19 Aug 2020 14:06:26
User entered 'No (N)'	System	19 Aug 2020 14:06:26

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:06:14', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '22caf863-2a94-4c9f-9e8c-8553906cb4ad'	System	19 Aug 2020 14:06:26
User entered 'No (N)'	System	19 Aug 2020 14:06:26

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:06:21', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '22caf863-2a94-4c9f-9e8c-8553906cb4ad'	System	19 Aug 2020 14:06:26
User entered 'None (1)'	System	19 Aug 2020 14:06:26

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:06:25', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '22caf863-2a94-4c9f-9e8c-8553906cb4ad'	System	19 Aug 2020 14:06:26
User entered '19 Aug 2020 10:06'	System	19 Aug 2020 14:06:26

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Aug 2020 09:56'	System	19 Aug 2020 13:39:34



**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Aug 2020 12:26'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:01:32', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ed796bed-2f9d-430a-be4c-1d2604b5f5bb'	System	19 Aug 2020 23:03:07
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 23:03:07

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:02:38', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ed796bed-2f9d-430a-be4c-1d2604b5f5bb' User entered 'No (N)'	System	19 Aug 2020 23:03:07
	System	19 Aug 2020 23:03:07

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:02:57', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ed796bed-2f9d-430a-be4c-1d2604b5f5bb' User entered 'No (N)'	System	19 Aug 2020 23:03:07
	System	19 Aug 2020 23:03:07

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:03:02', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ed796bed-2f9d-430a-be4c-1d2604b5f5bb' User entered 'None (1)'	System	19 Aug 2020 23:03:07
	System	19 Aug 2020 23:03:07

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:03:05', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ed796bed-2f9d-430a-be4c-1d2604b5f5bb'	System	19 Aug 2020 23:03:07
User entered '19 Aug 2020 19:03'	System	19 Aug 2020 23:03:07

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Aug 2020 13:21'	System	19 Aug 2020 13:39:34



US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 2'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:46:03', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '9b85d470-f930-4f14-bc80-2394ddef8a3a' User entered 'None (1)'	System	20 Aug 2020 22:46:15
	System	20 Aug 2020 22:46:15

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:46:05', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '9b85d470-f930-4f14-bc80-2394ddef8a3a' User entered 'No (N)'	System	20 Aug 2020 22:46:15
	System	20 Aug 2020 22:46:15

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:46:07', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '9b85d470-f930-4f14-bc80-2394ddef8a3a' User entered 'No (N)'	System	20 Aug 2020 22:46:15
	System	20 Aug 2020 22:46:15

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:46:11', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '9b85d470-f930-4f14-bc80-2394ddef8a3a' User entered 'None (1)'	System	20 Aug 2020 22:46:15
	System	20 Aug 2020 22:46:15

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:46:13', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '9b85d470-f930-4f14-bc80-2394ddef8a3a' User entered '20 Aug 2020 18:46'	System	20 Aug 2020 22:46:15
	System	20 Aug 2020 22:46:15

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 13:39:34



US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 3'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:10', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '877c368d-5c47-4117-a60b-5d7c571b26c6' User entered 'None (1)'	System	22 Aug 2020 01:22:20
	System	22 Aug 2020 01:22:20

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:13', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '877c368d-5c47-4117-a60b-5d7c571b26c6'	System	22 Aug 2020 01:22:20
User entered 'No (N)'	System	22 Aug 2020 01:22:20

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:15', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '877c368d-5c47-4117-a60b-5d7c571b26c6'	System	22 Aug 2020 01:22:20
User entered 'No (N)'	System	22 Aug 2020 01:22:20

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:17', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '877c368d-5c47-4117-a60b-5d7c571b26c6' User entered 'None (1)'	System	22 Aug 2020 01:22:20
	System	22 Aug 2020 01:22:20

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:19', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '877c368d-5c47-4117-a60b-5d7c571b26c6'	System	22 Aug 2020 01:22:20
User entered '21 Aug 2020 21:22'	System	22 Aug 2020 01:22:20

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 13:39:34



US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 4'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:38:31', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '618b6179-8a9c-481a-b07d-345b4bdb1810'	System	23 Aug 2020 13:38:40
User entered 'None (1)'	System	23 Aug 2020 13:38:40

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:38:32', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '618b6179-8a9c-481a-b07d-345b4bdb1810'	System	23 Aug 2020 13:38:40
User entered 'No (N)'	System	23 Aug 2020 13:38:40

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:38:34', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '618b6179-8a9c-481a-b07d-345b4bdb1810'	System	23 Aug 2020 13:38:40
User entered 'No (N)'	System	23 Aug 2020 13:38:40

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:38:36', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '618b6179-8a9c-481a-b07d-345b4bdb1810' User entered 'None (1)'	System	23 Aug 2020 13:38:40
	System	23 Aug 2020 13:38:40

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:38:38', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '618b6179-8a9c-481a-b07d-345b4bdb1810'	System	23 Aug 2020 13:38:40
User entered '23 Aug 2020 09:38'	System	23 Aug 2020 13:38:40

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 13:39:34



US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 5'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:49:48', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '65eaf305-5c82-46a6-8b71-314941d8467d' User entered 'None (1)'	System	24 Aug 2020 10:50:01
	System	24 Aug 2020 10:50:01

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:49:51', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '65eaf305-5c82-46a6-8b71-314941d8467d' User entered 'No (N)'	System	24 Aug 2020 10:50:01
	System	24 Aug 2020 10:50:01

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:49:52', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '65eaf305-5c82-46a6-8b71-314941d8467d' User entered 'No (N)'	System	24 Aug 2020 10:50:01
	System	24 Aug 2020 10:50:01

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:49:54', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '65eaf305-5c82-46a6-8b71-314941d8467d' User entered 'None (1)'	System	24 Aug 2020 10:50:01
	System	24 Aug 2020 10:50:01

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:49:57', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '65eaf305-5c82-46a6-8b71-314941d8467d' User entered '24 Aug 2020 06:49'	System	24 Aug 2020 10:50:01
	System	24 Aug 2020 10:50:01

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 13:39:34



**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 6'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:56:56', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '748b95bf-94d8-4675-b321-095974d283f4'	System	25 Aug 2020 12:57:06
User entered 'None (1)'	System	25 Aug 2020 12:57:06

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:56:58', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '748b95bf-94d8-4675-b321-095974d283f4' User entered 'No (N)'	System	25 Aug 2020 12:57:06
	System	25 Aug 2020 12:57:06

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:56:59', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '748b95bf-94d8-4675-b321-095974d283f4' User entered 'No (N)'	System	25 Aug 2020 12:57:06
	System	25 Aug 2020 12:57:06

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:57:01', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '748b95bf-94d8-4675-b321-095974d283f4'	System	25 Aug 2020 12:57:06
User entered 'None (1)'	System	25 Aug 2020 12:57:06

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:57:03', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '748b95bf-94d8-4675-b321-095974d283f4' User entered '25 Aug 2020 08:57'	System	25 Aug 2020 12:57:06
	System	25 Aug 2020 12:57:06

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 13:39:34



US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 7'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:09:49', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b6d22869-065f-47f3-a4d9-7afc551a9810' User entered 'None (1)'	System	26 Aug 2020 11:09:59
	System	26 Aug 2020 11:09:59

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:09:51', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b6d22869-065f-47f3-a4d9-7afc551a9810' User entered 'No (N)'	System	26 Aug 2020 11:09:59
	System	26 Aug 2020 11:09:59

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:09:52', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b6d22869-065f-47f3-a4d9-7afc551a9810' User entered 'No (N)'	System	26 Aug 2020 11:09:59
	System	26 Aug 2020 11:09:59

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:09:54', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b6d22869-065f-47f3-a4d9-7afc551a9810' User entered 'None (1)'	System	26 Aug 2020 11:09:59
	System	26 Aug 2020 11:09:59

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:09:56', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b6d22869-065f-47f3-a4d9-7afc551a9810' User entered '26 Aug 2020 07:09'	System	26 Aug 2020 11:09:59
	System	26 Aug 2020 11:09:59

US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 13:39:34



US3522200

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:06:31', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ffd618ba-537a-4754-acb9-2c2d28569736' User entered 'None (0)'	System	19 Aug 2020 14:07:04
	System	19 Aug 2020 14:07:04

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:06:43', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ffd618ba-537a-4754-acb9-2c2d28569736' User entered 'None (0)'	System	19 Aug 2020 14:07:04
	System	19 Aug 2020 14:07:04

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:06:46', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ffd618ba-537a-4754-acb9-2c2d28569736' User entered 'None (0)'	System	19 Aug 2020 14:07:04
	System	19 Aug 2020 14:07:04

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:06:48', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ffd618ba-537a-4754-acb9-2c2d28569736' User entered 'None (0)'	System	19 Aug 2020 14:07:04
	System	19 Aug 2020 14:07:04

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:06:50', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ffd618ba-537a-4754-acb9-2c2d28569736' User entered 'None (0)'	System	19 Aug 2020 14:07:04
	System	19 Aug 2020 14:07:04

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:06:52', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ffd618ba-537a-4754-acb9-2c2d28569736' User entered 'None (0)'	System	19 Aug 2020 14:07:04
	System	19 Aug 2020 14:07:04



US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:06:57', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ffd618ba-537a-4754-acb9-2c2d28569736' User entered 'No (N)'	System	19 Aug 2020 14:07:04
	System	19 Aug 2020 14:07:04

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T10:07:01', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ffd618ba-537a-4754-acb9-2c2d28569736' User entered '19 Aug 2020 10:07'	System	19 Aug 2020 14:07:04
	System	19 Aug 2020 14:07:04

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Aug 2020 09:56'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Aug 2020 12:26'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:03:24', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '21f35f57-c7c2-45db-bd24-6b295f3079c9'	System	19 Aug 2020 23:03:55
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Aug 2020 23:03:55

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:03:29', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '21f35f57-c7c2-45db-bd24-6b295f3079c9'	System	19 Aug 2020 23:03:55
User entered 'Some interference with activity (2)'	System	19 Aug 2020 23:03:55

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:03:34', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '21f35f57-c7c2-45db-bd24-6b295f3079c9' User entered 'None (0)'	System	19 Aug 2020 23:03:55
	System	19 Aug 2020 23:03:55



**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:11**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:03:37', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '21f35f57-c7c2-45db-bd24-6b295f3079c9' User entered 'None (0)'	System	19 Aug 2020 23:03:55
	System	19 Aug 2020 23:03:55

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:03:40', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '21f35f57-c7c2-45db-bd24-6b295f3079c9' User entered 'None (0)'	System	19 Aug 2020 23:03:55
	System	19 Aug 2020 23:03:55

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:03:45', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '21f35f57-c7c2-45db-bd24-6b295f3079c9' User entered 'None (0)'	System	19 Aug 2020 23:03:55
	System	19 Aug 2020 23:03:55

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:03:49', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '21f35f57-c7c2-45db-bd24-6b295f3079c9' User entered 'No (N)'	System	19 Aug 2020 23:03:55
	System	19 Aug 2020 23:03:55

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-19T19:03:51', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '21f35f57-c7c2-45db-bd24-6b295f3079c9' User entered '19 Aug 2020 19:03'	System	19 Aug 2020 23:03:55
	System	19 Aug 2020 23:03:55

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Aug 2020 13:21'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 2'	System	19 Aug 2020 13:39:34



US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:46:18', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '977e80ff-7a88-4859-b4c2-1f96c3c22693' User entered 'None (0)'	System	20 Aug 2020 22:46:36
	System	20 Aug 2020 22:46:36

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:46:21', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '977e80ff-7a88-4859-b4c2-1f96c3c22693'	System	20 Aug 2020 22:46:36
User entered 'None (0)'	System	20 Aug 2020 22:46:36

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:46:23', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '977e80ff-7a88-4859-b4c2-1f96c3c22693' User entered 'None (0)'	System	20 Aug 2020 22:46:36
	System	20 Aug 2020 22:46:36

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:46:25', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '977e80ff-7a88-4859-b4c2-1f96c3c22693' User entered 'None (0)'	System	20 Aug 2020 22:46:36
	System	20 Aug 2020 22:46:36

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:46:26', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '977e80ff-7a88-4859-b4c2-1f96c3c22693' User entered 'None (0)'	System	20 Aug 2020 22:46:36
	System	20 Aug 2020 22:46:36

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:46:28', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '977e80ff-7a88-4859-b4c2-1f96c3c22693' User entered 'None (0)'	System	20 Aug 2020 22:46:36
	System	20 Aug 2020 22:46:36

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:46:30', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '977e80ff-7a88-4859-b4c2-1f96c3c22693'	System	20 Aug 2020 22:46:36
User entered 'No (N)'	System	20 Aug 2020 22:46:36

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-20T18:46:32', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '977e80ff-7a88-4859-b4c2-1f96c3c22693'	System	20 Aug 2020 22:46:36
User entered '20 Aug 2020 18:46'	System	20 Aug 2020 22:46:36



**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 3'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:22', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b02e7e50-0e93-4433-9983-cceca7fbaa32'	System	22 Aug 2020 01:22:38
User entered 'None (0)'	System	22 Aug 2020 01:22:38

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:24', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b02e7e50-0e93-4433-9983-cceca7fbaa32' User entered 'None (0)'	System	22 Aug 2020 01:22:38
	System	22 Aug 2020 01:22:38

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:26', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b02e7e50-0e93-4433-9983-cceca7fbaa32' User entered 'None (0)'	System	22 Aug 2020 01:22:38
	System	22 Aug 2020 01:22:38

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:28', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b02e7e50-0e93-4433-9983-cceca7fbaa32' User entered 'None (0)'	System	22 Aug 2020 01:22:38
	System	22 Aug 2020 01:22:38

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:29', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b02e7e50-0e93-4433-9983-cceca7fbaa32' User entered 'None (0)'	System	22 Aug 2020 01:22:38
	System	22 Aug 2020 01:22:38



US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:31', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b02e7e50-0e93-4433-9983-cceca7fbaa32' User entered 'None (0)'	System	22 Aug 2020 01:22:38
	System	22 Aug 2020 01:22:38

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:33', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b02e7e50-0e93-4433-9983-cceca7fbaa32'	System	22 Aug 2020 01:22:38
User entered 'No (N)'	System	22 Aug 2020 01:22:38

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-21T21:22:34', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b02e7e50-0e93-4433-9983-cceca7fbaa32' User entered '21 Aug 2020 21:22'	System	22 Aug 2020 01:22:38
	System	22 Aug 2020 01:22:38

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 4'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:38:41', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'acc82f97-575e-41b5-94be-2ba9ea72f2ac' User entered 'None (0)'	System	23 Aug 2020 13:38:54
	System	23 Aug 2020 13:38:54

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:38:42', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'acc82f97-575e-41b5-94be-2ba9ea72f2ac' User entered 'None (0)'	System	23 Aug 2020 13:38:54
	System	23 Aug 2020 13:38:54



US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:38:43', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'acc82f97-575e-41b5-94be-2ba9ea72f2ac' User entered 'None (0)'	System	23 Aug 2020 13:38:54
	System	23 Aug 2020 13:38:54

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:38:45', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'acc82f97-575e-41b5-94be-2ba9ea72f2ac' User entered 'None (0)'	System	23 Aug 2020 13:38:54
	System	23 Aug 2020 13:38:54

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:38:46', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'acc82f97-575e-41b5-94be-2ba9ea72f2ac' User entered 'None (0)'	System	23 Aug 2020 13:38:54
	System	23 Aug 2020 13:38:54

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:38:47', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'acc82f97-575e-41b5-94be-2ba9ea72f2ac' User entered 'None (0)'	System	23 Aug 2020 13:38:54
	System	23 Aug 2020 13:38:54

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:38:50', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'acc82f97-575e-41b5-94be-2ba9ea72f2ac'	System	23 Aug 2020 13:38:54
User entered 'No (N)'	System	23 Aug 2020 13:38:54

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-23T09:38:51', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'acc82f97-575e-41b5-94be-2ba9ea72f2ac' User entered '23 Aug 2020 09:38'	System	23 Aug 2020 13:38:54
	System	23 Aug 2020 13:38:54

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 13:39:34



**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 5'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:50:14', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ff0d78a3-3821-425e-b28c-a15a2b6b8eda' User entered 'None (0)'	System	24 Aug 2020 10:50:33
	System	24 Aug 2020 10:50:33

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:50:17', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ff0d78a3-3821-425e-b28c-a15a2b6b8eda' User entered 'None (0)'	System	24 Aug 2020 10:50:33
	System	24 Aug 2020 10:50:33

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:50:19', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ff0d78a3-3821-425e-b28c-a15a2b6b8eda' User entered 'None (0)'	System	24 Aug 2020 10:50:33
	System	24 Aug 2020 10:50:33

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:50:21', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ff0d78a3-3821-425e-b28c-a15a2b6b8eda' User entered 'None (0)'	System	24 Aug 2020 10:50:33
	System	24 Aug 2020 10:50:33

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:50:22', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ff0d78a3-3821-425e-b28c-a15a2b6b8eda' User entered 'None (0)'	System	24 Aug 2020 10:50:33
	System	24 Aug 2020 10:50:33

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:50:24', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ff0d78a3-3821-425e-b28c-a15a2b6b8eda' User entered 'None (0)'	System	24 Aug 2020 10:50:33
	System	24 Aug 2020 10:50:33

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:50:26', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ff0d78a3-3821-425e-b28c-a15a2b6b8eda' User entered 'No (N)'	System	24 Aug 2020 10:50:33
	System	24 Aug 2020 10:50:33



**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-24T06:50:28', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ff0d78a3-3821-425e-b28c-a15a2b6b8eda' User entered '24 Aug 2020 06:50'	System	24 Aug 2020 10:50:33
	System	24 Aug 2020 10:50:33

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 6'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:57:06', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3f7e0e1c-ef8a-4ca8-acec-af9436b4b84d' User entered 'None (0)'	System	25 Aug 2020 12:57:23
	System	25 Aug 2020 12:57:23

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:57:08', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3f7e0e1c-ef8a-4ca8-acec-af9436b4b84d' User entered 'None (0)'	System	25 Aug 2020 12:57:23
	System	25 Aug 2020 12:57:23

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:57:10', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3f7e0e1c-ef8a-4ca8-acec-af9436b4b84d' User entered 'None (0)'	System	25 Aug 2020 12:57:23
	System	25 Aug 2020 12:57:23

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:57:11', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3f7e0e1c-ef8a-4ca8-acec-af9436b4b84d' User entered 'None (0)'	System	25 Aug 2020 12:57:23
	System	25 Aug 2020 12:57:23



US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:57:13', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3f7e0e1c-ef8a-4ca8-acec-af9436b4b84d' User entered 'None (0)'	System	25 Aug 2020 12:57:23
	System	25 Aug 2020 12:57:23

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:57:14', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3f7e0e1c-ef8a-4ca8-acec-af9436b4b84d' User entered 'None (0)'	System	25 Aug 2020 12:57:23
	System	25 Aug 2020 12:57:23

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:57:16', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3f7e0e1c-ef8a-4ca8-acec-af9436b4b84d' User entered 'No (N)'	System	25 Aug 2020 12:57:23
	System	25 Aug 2020 12:57:23

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-25T08:57:18', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3f7e0e1c-ef8a-4ca8-acec-af9436b4b84d' User entered '25 Aug 2020 08:57'	System	25 Aug 2020 12:57:23
	System	25 Aug 2020 12:57:23

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 7'	System	19 Aug 2020 13:39:34

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:09:59', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '533c2501-ccc0-4786-81a0-5d54c73b6ce9' User entered 'None (0)'	System	26 Aug 2020 11:10:17
	System	26 Aug 2020 11:10:17



US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:10:01', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '533c2501-ccc0-4786-81a0-5d54c73b6ce9' User entered 'None (0)'	System	26 Aug 2020 11:10:17
	System	26 Aug 2020 11:10:17

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:10:02', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '533c2501-ccc0-4786-81a0-5d54c73b6ce9' User entered 'None (0)'	System	26 Aug 2020 11:10:17
	System	26 Aug 2020 11:10:17

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:10:07', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '533c2501-ccc0-4786-81a0-5d54c73b6ce9' User entered 'None (0)'	System	26 Aug 2020 11:10:17
	System	26 Aug 2020 11:10:17

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:10:08', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '533c2501-ccc0-4786-81a0-5d54c73b6ce9' User entered 'None (0)'	System	26 Aug 2020 11:10:17
	System	26 Aug 2020 11:10:17

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:10:11', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '533c2501-ccc0-4786-81a0-5d54c73b6ce9' User entered 'None (0)'	System	26 Aug 2020 11:10:17
	System	26 Aug 2020 11:10:17

US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:10:13', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '533c2501-ccc0-4786-81a0-5d54c73b6ce9' User entered 'No (N)'	System	26 Aug 2020 11:10:17
	System	26 Aug 2020 11:10:17

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-08-26T07:10:15', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '533c2501-ccc0-4786-81a0-5d54c73b6ce9' User entered '26 Aug 2020 07:10'	System	26 Aug 2020 11:10:17
	System	26 Aug 2020 11:10:17

**US3522200**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 13:39:34



US3522200

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 13:39:34

**US3522200**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:08:06

**US3522200**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '26 Aug 2020'	Yaman Ahmed (b) (4)	26 Aug 2020 14:08:06

US3522200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Contact Made (CONTACT MADE)'	Yaman Ahmed (b) (4)	26 Aug 2020 14:08:06

US3522200

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Aleve taken at home the day of injection for pain in both arms from blood draw and injection and also experienced some fatigue the same day; both AE resolved by the next day.'	Yaman Ahmed (b) (4)	26 Aug 2020 14:08:06

**US3522200**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:08:12

**US3522200**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'I'	System	26 Aug 2020 14:08:12

**US3522200**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	02 Sep 2020 14:36:26



**US3522200**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '2 Sep 2020'	Yaman Ahmed (b) (4)	02 Sep 2020 14:36:26

**US3522200**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	02 Sep 2020 14:36:26

US3522200

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk'	(b) (4) Yaman Ahmed (b) (4)	02 Sep 2020 14:36:26

US3522200

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	02 Sep 2020 14:36:31

**US3522200**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'I'	System	02 Sep 2020 14:36:31

**US3522200**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	09 Sep 2020 14:31:45

**US3522200**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '9 Sep 2020'	(b) (4) Yaman Ahmed (b) (4)	09 Sep 2020 14:31:45

**US3522200**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	09 Sep 2020 14:31:45



US3522200

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk'	(b) (4) Yaman Ahmed (b) (4)	09 Sep 2020 14:31:45

US3522200

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	09 Sep 2020 14:31:52

**US3522200**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'I'	System	09 Sep 2020 14:31:52

US3522200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Sep 2020 21:01:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Sep 2020 21:01:03
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	14 Sep 2020 19:25:52
	Sharon Mathys (b) (4)	14 Sep 2020 19:25:52
	(b) (4)	

US3522200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Sharon Mathys (b) (4)	26 Sep 2020 21:01:03
User entered empty.	(b) (4)	
	Sharon Mathys (b) (4)	14 Sep 2020 19:25:52
	(b) (4)	

US3522200

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered 'Clinic (Clinic)' reason for change:	(b) (4)	
Data Entry Error	Sharon Mathys (b) (4)	26 Sep 2020 21:01:03
User entered empty.	(b) (4)	
	Sharon Mathys (b) (4)	14 Sep 2020 19:25:52
	(b) (4)	

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'VISIT2'	System	26 Sep 2020 21:01:03
User entered empty.	System	14 Sep 2020 19:25:52

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User accepted default value 'Pre-Dose (PREDOSE)'	Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 17:44:54



US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '18 Sep 2020'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:44:54

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '13:45'	Alayna Wilder (b) (4)	18 Sep 2020 17:44:54

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered '18 Sep 2020 13:45'	System	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '98.1' F	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered 'Other (Other)'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered 'temporal'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:44:54

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '76'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:44:54



US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered 'bpm'	System	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '20'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered 'breaths/min'	System	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '134'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered 'mmHg'	System	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '85'	(b) (4) Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered 'mmHg'	System	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User accepted default value 'Post-Dose (POSTDOSE)'	Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 17:44:54



US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	18 Sep 2020 18:53:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Sep 2020 18:53:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 18:53:38
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Sep 2020 17:44:54
User entered empty.	Alayna Wilder (b) (4)	18 Sep 2020 17:44:54
	(b) (4)	

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '18 Sep 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:53:38
User entered empty.	Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '14:45' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:53:38
User entered empty.	Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered '18 Sep 2020 14:45'	System	18 Sep 2020 18:53:38
User entered empty.	System	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '98.2' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:53:38
User entered empty.	Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:53:38
User entered empty.	Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered 'Temporal' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:53:38
User entered empty.	Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '71' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:53:38
User entered empty.	Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 17:44:54



**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered 'bpm'	System	18 Sep 2020 18:53:38
User entered empty.	System	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '14' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:53:38
User entered empty.	Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered 'breaths/min'	System	18 Sep 2020 18:53:38
User entered empty.	System	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '124' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:53:38
User entered empty.	Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered 'mmHg'	System	18 Sep 2020 18:53:38
User entered empty.	System	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '87' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:53:38
User entered empty.	Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered 'mmHg'	System	18 Sep 2020 18:53:38
User entered empty.	System	18 Sep 2020 17:44:54

US3522200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:37:29



US3522200

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '18 Sep 2020'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:37:29

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:48:21

US3522200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:11

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '18 Sep 2020'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:48:21

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Urine (URINE)'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:48:21

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Negative (NEGATIVE)'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:48:21

US3522200

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:11

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'No (N)'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:48:21

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered empty.	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:48:21

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered empty.	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 17:48:21



**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered empty.	System	18 Sep 2020 17:48:21

US3522200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:22:03

US3522200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:22:03

US3522200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

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)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:22:03

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:11**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 18:22:03

US3522200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:22:03

US3522200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '13:50'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:22:03

US3522200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered '18 Sep 2020 13:50'	System	18 Sep 2020 18:22:03



US3522200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) System	18 Sep 2020 18:22:09
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	18 Sep 2020 18:22:09
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 18:22:09
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	18 Sep 2020 18:22:03
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	18 Sep 2020 18:22:03

US3522200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'ONCE'	System	18 Sep 2020 18:22:03

US3522200

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 18:22:03

US3522200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 18:43:00

US3522200

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '18 Sep 2020'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 18:43:00

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:11**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '13:58'	Alayna Wilder (b) (4)	18 Sep 2020 18:43:00

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered '18 Sep 2020 13:58'	System	18 Sep 2020 18:43:00

US3522200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:56:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '18 Sep 2020'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 18:43:18



**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 18:43:18

US3522200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:56:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 18:43:18

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:56:11**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '14:02'	(b) (4) Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 18:43:18

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered '18 Sep 2020 14:02'	System	18 Sep 2020 18:43:18

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alayna Wilder (b) (4) (b) (4)	18 Sep 2020 18:43:18

US3522200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:56:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'No (N)'	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 18:43:18

US3522200

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:56:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered empty.	(b) (4) Alayna Wilder (b) (4)	18 Sep 2020 18:43:18

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered empty.	System	18 Sep 2020 18:43:18



US3522200

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:53:48

**US3522200**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'I'	System	18 Sep 2020 18:53:48

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:46:16', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '0496bae2-df34-4387-b437-a64e048f032b' User entered 'Yes (Y)'	System	18 Sep 2020 18:46:28
	System	18 Sep 2020 18:46:28

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:46:19', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '0496bae2-df34-4387-b437-a64e048f032b' User entered '98.2'	System	18 Sep 2020 18:46:28
	System	18 Sep 2020 18:46:28

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:46:24', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '0496bae2-df34-4387-b437-a64e048f032b' User entered 'No (N)'	System	18 Sep 2020 18:46:28
	System	18 Sep 2020 18:46:28

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:46:27', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '0496bae2-df34-4387-b437-a64e048f032b' User entered '18 Sep 2020 14:46'	System	18 Sep 2020 18:46:28
	System	18 Sep 2020 18:46:28

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '18 Sep 2020 14:10'	System	18 Sep 2020 18:22:03



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '18 Sep 2020 16:40'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:08:46', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'f1691855-8e0e-42dc-978f-227b61553ece' User entered 'Yes (Y)'	System	19 Sep 2020 14:10:30
	System	19 Sep 2020 14:10:30

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:10:21', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'f1691855-8e0e-42dc-978f-227b61553ece' User entered '98.8'	System	19 Sep 2020 14:10:30
	System	19 Sep 2020 14:10:30

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:10:25', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'f1691855-8e0e-42dc-978f-227b61553ece' User entered 'No (N)'	System	19 Sep 2020 14:10:30
	System	19 Sep 2020 14:10:30

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:10:28', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'f1691855-8e0e-42dc-978f-227b61553ece' User entered '19 Sep 2020 10:10'	System	19 Sep 2020 14:10:30
	System	19 Sep 2020 14:10:30

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '18 Sep 2020 17:35'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:22:03



US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 2'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:33:19', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '7b7fbe11-b75f-43a6-9d3f-5db00a215fd4' User entered 'Yes (Y)'	System	20 Sep 2020 15:33:58
	System	20 Sep 2020 15:33:58

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:33:51', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '7b7fbe11-b75f-43a6-9d3f-5db00a215fd4' User entered '97.2'	System	20 Sep 2020 15:33:58
	System	20 Sep 2020 15:33:58

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:33:54', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '7b7fbe11-b75f-43a6-9d3f-5db00a215fd4'	System	20 Sep 2020 15:33:58
User entered 'No (N)'	System	20 Sep 2020 15:33:58

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:33:57', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '7b7fbe11-b75f-43a6-9d3f-5db00a215fd4' User entered '20 Sep 2020 11:33'	System	20 Sep 2020 15:33:58
	System	20 Sep 2020 15:33:58

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 3'	System	18 Sep 2020 18:22:03



US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:43:30', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '1e23f6ad-8cc6-49a8-b05e-0823878edbeb' User entered 'Yes (Y)'	System	21 Sep 2020 11:43:53
	System	21 Sep 2020 11:43:53

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:43:44', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '1e23f6ad-8cc6-49a8-b05e-0823878edbeb' User entered '97.9'	System	21 Sep 2020 11:43:53
	System	21 Sep 2020 11:43:53

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:43:46', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '1e23f6ad-8cc6-49a8-b05e-0823878edbeb' User entered 'No (N)'	System	21 Sep 2020 11:43:53
	System	21 Sep 2020 11:43:53

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:43:48', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '1e23f6ad-8cc6-49a8-b05e-0823878edbeb' User entered '21 Sep 2020 07:43'	System	21 Sep 2020 11:43:53
	System	21 Sep 2020 11:43:53

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 4'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:58:45', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '0ed7332d-d023-4779-a542-b22b4ea7f9c5' User entered 'Yes (Y)'	System	22 Sep 2020 13:00:03
	System	22 Sep 2020 13:00:03



US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:59:47', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '0ed7332d-d023-4779-a542-b22b4ea7f9c5' User entered '99.0'	System	22 Sep 2020 13:00:03
	System	22 Sep 2020 13:00:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:59:52', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '0ed7332d-d023-4779-a542-b22b4ea7f9c5'	System	22 Sep 2020 13:00:03
User entered 'No (N)'	System	22 Sep 2020 13:00:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:59:56', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '0ed7332d-d023-4779-a542-b22b4ea7f9c5' User entered '22 Sep 2020 08:59'	System	22 Sep 2020 13:00:03
	System	22 Sep 2020 13:00:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 5'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:15:55', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '76028c4d-1253-4c72-879c-2435d338562f' User entered 'Yes (Y)'	System	23 Sep 2020 11:16:26
	System	23 Sep 2020 11:16:26

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:16:19', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '76028c4d-1253-4c72-879c-2435d338562f' User entered '98.6'	System	23 Sep 2020 11:16:26
	System	23 Sep 2020 11:16:26



US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:16:21', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '76028c4d-1253-4c72-879c-2435d338562f' User entered 'No (N)'	System	23 Sep 2020 11:16:26
	System	23 Sep 2020 11:16:26

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:16:23', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '76028c4d-1253-4c72-879c-2435d338562f' User entered '23 Sep 2020 07:16'	System	23 Sep 2020 11:16:26
	System	23 Sep 2020 11:16:26

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 6'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:26', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'd0675649-48c0-414a-bee5-fa4f52ae1659' User entered 'Yes (Y)'	System	24 Sep 2020 13:06:58
	System	24 Sep 2020 13:06:58

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:50', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'd0675649-48c0-414a-bee5-fa4f52ae1659' User entered '98.8'	System	24 Sep 2020 13:06:58
	System	24 Sep 2020 13:06:58

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:53', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'd0675649-48c0-414a-bee5-fa4f52ae1659' User entered 'No (N)'	System	24 Sep 2020 13:06:58
	System	24 Sep 2020 13:06:58



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:54', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'd0675649-48c0-414a-bee5-fa4f52ae1659' User entered '24 Sep 2020 09:06'	System	24 Sep 2020 13:06:58
	System	24 Sep 2020 13:06:58

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 7'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:55:14', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '20c7eee9-f024-432f-8313-72368e709e3a' User entered 'Yes (Y)'	System	25 Sep 2020 13:55:56
	System	25 Sep 2020 13:55:56

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:55:49', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '20c7eee9-f024-432f-8313-72368e709e3a' User entered '99.2'	System	25 Sep 2020 13:55:56
	System	25 Sep 2020 13:55:56

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:55:53', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '20c7eee9-f024-432f-8313-72368e709e3a' User entered 'No (N)'	System	25 Sep 2020 13:55:56
	System	25 Sep 2020 13:55:56

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:55:55', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '20c7eee9-f024-432f-8313-72368e709e3a' User entered '25 Sep 2020 09:55'	System	25 Sep 2020 13:55:56
	System	25 Sep 2020 13:55:56



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:46:41', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cc17cca0-661a-410d-9c5c-731ef81610ec'	System	18 Sep 2020 18:47:23
User entered 'None (1)'	System	18 Sep 2020 18:47:23

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:47:11', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cc17cca0-661a-410d-9c5c-731ef81610ec' User entered 'No (N)'	System	18 Sep 2020 18:47:23
	System	18 Sep 2020 18:47:23

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:47:14', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cc17cca0-661a-410d-9c5c-731ef81610ec' User entered 'No (N)'	System	18 Sep 2020 18:47:23
	System	18 Sep 2020 18:47:23

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:47:19', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cc17cca0-661a-410d-9c5c-731ef81610ec'	System	18 Sep 2020 18:47:23
User entered 'None (1)'	System	18 Sep 2020 18:47:23

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:47:21', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cc17cca0-661a-410d-9c5c-731ef81610ec'	System	18 Sep 2020 18:47:23
User entered '18 Sep 2020 14:47'	System	18 Sep 2020 18:47:23



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '18 Sep 2020 14:10'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '18 Sep 2020 16:40'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:10:40', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '615a8c19-1159-4133-b8fb-6eaa597a4044'	System	19 Sep 2020 14:10:54
User entered 'None (1)'	System	19 Sep 2020 14:10:54

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:10:42', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '615a8c19-1159-4133-b8fb-6eaa597a4044' User entered 'No (N)'	System	19 Sep 2020 14:10:54
	System	19 Sep 2020 14:10:54

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:10:47', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '615a8c19-1159-4133-b8fb-6eaa597a4044' User entered 'No (N)'	System	19 Sep 2020 14:10:54
	System	19 Sep 2020 14:10:54

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:10:49', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '615a8c19-1159-4133-b8fb-6eaa597a4044'	System	19 Sep 2020 14:10:54
User entered 'None (1)'	System	19 Sep 2020 14:10:54

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:10:51', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '615a8c19-1159-4133-b8fb-6eaa597a4044'	System	19 Sep 2020 14:10:54
User entered '19 Sep 2020 10:10'	System	19 Sep 2020 14:10:54



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '18 Sep 2020 17:35'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 2'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:32:47', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'f9222e0e-6fdb-4eda-8fe9-2570f36560e2'	System	20 Sep 2020 15:32:59
User entered 'None (1)'	System	20 Sep 2020 15:32:59

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:32:50', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'f9222e0e-6fdb-4eda-8fe9-2570f36560e2' User entered 'No (N)'	System	20 Sep 2020 15:32:59
	System	20 Sep 2020 15:32:59

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:32:54', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'f9222e0e-6fdb-4eda-8fe9-2570f36560e2' User entered 'No (N)'	System	20 Sep 2020 15:32:59
	System	20 Sep 2020 15:32:59

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:32:56', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'f9222e0e-6fdb-4eda-8fe9-2570f36560e2'	System	20 Sep 2020 15:32:59
User entered 'None (1)'	System	20 Sep 2020 15:32:59

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:32:58', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'f9222e0e-6fdb-4eda-8fe9-2570f36560e2' User entered '20 Sep 2020 11:32'	System	20 Sep 2020 15:32:59
	System	20 Sep 2020 15:32:59



US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 3'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:42:38', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'aab319b8-7230-48be-9637-82dc5c6cd7bf' User entered 'None (1)'	System	21 Sep 2020 11:43:06
	System	21 Sep 2020 11:43:06

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:42:49', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'aab319b8-7230-48be-9637-82dc5c6cd7bf' User entered 'No (N)'	System	21 Sep 2020 11:43:06
	System	21 Sep 2020 11:43:06

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:42:55', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'aab319b8-7230-48be-9637-82dc5c6cd7bf' User entered 'No (N)'	System	21 Sep 2020 11:43:06
	System	21 Sep 2020 11:43:06

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:43:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'aab319b8-7230-48be-9637-82dc5c6cd7bf' User entered 'None (1)'	System	21 Sep 2020 11:43:06
	System	21 Sep 2020 11:43:06

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:43:02', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'aab319b8-7230-48be-9637-82dc5c6cd7bf' User entered '21 Sep 2020 07:43'	System	21 Sep 2020 11:43:06
	System	21 Sep 2020 11:43:06



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 4'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:58:17', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '4a8d5a4e-7429-4aa3-a92a-f999d0265cc5' User entered 'None (1)'	System	22 Sep 2020 12:58:29
	System	22 Sep 2020 12:58:29

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:58:20', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '4a8d5a4e-7429-4aa3-a92a-f999d0265cc5' User entered 'No (N)'	System	22 Sep 2020 12:58:29
	System	22 Sep 2020 12:58:29

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:58:22', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '4a8d5a4e-7429-4aa3-a92a-f999d0265cc5' User entered 'No (N)'	System	22 Sep 2020 12:58:29
	System	22 Sep 2020 12:58:29

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:58:23', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '4a8d5a4e-7429-4aa3-a92a-f999d0265cc5' User entered 'None (1)'	System	22 Sep 2020 12:58:29
	System	22 Sep 2020 12:58:29

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:58:25', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '4a8d5a4e-7429-4aa3-a92a-f999d0265cc5' User entered '22 Sep 2020 08:58'	System	22 Sep 2020 12:58:29
	System	22 Sep 2020 12:58:29



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 5'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:15:26', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '1604c86a-3bc1-42d3-8cb7-11931862c981' User entered 'None (1)'	System	23 Sep 2020 11:15:38
	System	23 Sep 2020 11:15:38

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:15:29', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '1604c86a-3bc1-42d3-8cb7-11931862c981' User entered 'No (N)'	System	23 Sep 2020 11:15:38
	System	23 Sep 2020 11:15:38

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:15:32', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '1604c86a-3bc1-42d3-8cb7-11931862c981' User entered 'No (N)'	System	23 Sep 2020 11:15:38
	System	23 Sep 2020 11:15:38

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:15:34', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '1604c86a-3bc1-42d3-8cb7-11931862c981' User entered 'None (1)'	System	23 Sep 2020 11:15:38
	System	23 Sep 2020 11:15:38

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:15:36', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '1604c86a-3bc1-42d3-8cb7-11931862c981' User entered '23 Sep 2020 07:15'	System	23 Sep 2020 11:15:38
	System	23 Sep 2020 11:15:38



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 6'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:05:58', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'fe05685c-30c5-47cf-b6ff-7f2c165ac0b4'	System	24 Sep 2020 13:06:12
User entered 'None (1)'	System	24 Sep 2020 13:06:12

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:01', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'fe05685c-30c5-47cf-b6ff-7f2c165ac0b4'	System	24 Sep 2020 13:06:12
User entered 'No (N)'	System	24 Sep 2020 13:06:12

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:03', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'fe05685c-30c5-47cf-b6ff-7f2c165ac0b4' User entered 'No (N)'	System	24 Sep 2020 13:06:12
	System	24 Sep 2020 13:06:12

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:05', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'fe05685c-30c5-47cf-b6ff-7f2c165ac0b4' User entered 'None (1)'	System	24 Sep 2020 13:06:12
	System	24 Sep 2020 13:06:12

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:08', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'fe05685c-30c5-47cf-b6ff-7f2c165ac0b4' User entered '24 Sep 2020 09:06'	System	24 Sep 2020 13:06:12
	System	24 Sep 2020 13:06:12



US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:56:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 7'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:55:04', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'af0fb884-c8cd-4563-b161-a770fad36add' User entered 'None (1)'	System	25 Sep 2020 13:55:13
	System	25 Sep 2020 13:55:13

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:55:06', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'af0fb884-c8cd-4563-b161-a770fad36add' User entered 'No (N)'	System	25 Sep 2020 13:55:13
	System	25 Sep 2020 13:55:13

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:55:07', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'af0fb884-c8cd-4563-b161-a770fad36add'	System	25 Sep 2020 13:55:13
User entered 'No (N)'	System	25 Sep 2020 13:55:13

US3522200

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:56:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:55:08', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'af0fb884-c8cd-4563-b161-a770fad36add' User entered 'None (1)'	System	25 Sep 2020 13:55:13
	System	25 Sep 2020 13:55:13

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:55:10', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'af0fb884-c8cd-4563-b161-a770fad36add' User entered '25 Sep 2020 09:55'	System	25 Sep 2020 13:55:13
	System	25 Sep 2020 13:55:13



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:47:26', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'a659a890-b0ea-4ed9-a397-f08575189f59' User entered 'None (0)'	System	18 Sep 2020 18:47:55
	System	18 Sep 2020 18:47:55

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:47:37', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'a659a890-b0ea-4ed9-a397-f08575189f59' User entered 'None (0)'	System	18 Sep 2020 18:47:55
	System	18 Sep 2020 18:47:55

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:47:39', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'a659a890-b0ea-4ed9-a397-f08575189f59' User entered 'None (0)'	System	18 Sep 2020 18:47:55
	System	18 Sep 2020 18:47:55

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:47:41', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'a659a890-b0ea-4ed9-a397-f08575189f59' User entered 'None (0)'	System	18 Sep 2020 18:47:55
	System	18 Sep 2020 18:47:55

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:47:43', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'a659a890-b0ea-4ed9-a397-f08575189f59' User entered 'None (0)'	System	18 Sep 2020 18:47:55
	System	18 Sep 2020 18:47:55



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:47:45', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'a659a890-b0ea-4ed9-a397-f08575189f59' User entered 'None (0)'	System	18 Sep 2020 18:47:55
	System	18 Sep 2020 18:47:55

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:47:49', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'a659a890-b0ea-4ed9-a397-f08575189f59' User entered 'No (N)'	System	18 Sep 2020 18:47:55
	System	18 Sep 2020 18:47:55

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-18T14:47:52', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'a659a890-b0ea-4ed9-a397-f08575189f59' User entered '18 Sep 2020 14:47'	System	18 Sep 2020 18:47:55
	System	18 Sep 2020 18:47:55

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '18 Sep 2020 14:10'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '18 Sep 2020 16:40'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:11:01', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e4b9d1a1-173e-42c3-b07e-e22b7e6c7def' User entered 'None (0)'	System	19 Sep 2020 14:11:17
	System	19 Sep 2020 14:11:17

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:11:04', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e4b9d1a1-173e-42c3-b07e-e22b7e6c7def' User entered 'None (0)'	System	19 Sep 2020 14:11:17
	System	19 Sep 2020 14:11:17



US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:11:06', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e4b9d1a1-173e-42c3-b07e-e22b7e6c7def' User entered 'None (0)'	System	19 Sep 2020 14:11:17
	System	19 Sep 2020 14:11:17

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:11:07', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e4b9d1a1-173e-42c3-b07e-e22b7e6c7def' User entered 'None (0)'	System	19 Sep 2020 14:11:17
	System	19 Sep 2020 14:11:17

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:11:09', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e4b9d1a1-173e-42c3-b07e-e22b7e6c7def' User entered 'None (0)'	System	19 Sep 2020 14:11:17
	System	19 Sep 2020 14:11:17

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:11:10', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e4b9d1a1-173e-42c3-b07e-e22b7e6c7def' User entered 'None (0)'	System	19 Sep 2020 14:11:17
	System	19 Sep 2020 14:11:17

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:11:14', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e4b9d1a1-173e-42c3-b07e-e22b7e6c7def' User entered 'No (N)'	System	19 Sep 2020 14:11:17
	System	19 Sep 2020 14:11:17

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-19T10:11:16', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e4b9d1a1-173e-42c3-b07e-e22b7e6c7def' User entered '19 Sep 2020 10:11'	System	19 Sep 2020 14:11:17
	System	19 Sep 2020 14:11:17

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '18 Sep 2020 17:35'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:56:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 18:22:03



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 2'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:33:01', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cea068ec-b5bd-40ff-aaa1-83ab599bdff4' User entered 'None (0)'	System	20 Sep 2020 15:33:16
	System	20 Sep 2020 15:33:16

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:33:03', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cea068ec-b5bd-40ff-aaa1-83ab599bdff4' User entered 'None (0)'	System	20 Sep 2020 15:33:16
	System	20 Sep 2020 15:33:16

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:33:05', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cea068ec-b5bd-40ff-aaa1-83ab599bdff4' User entered 'None (0)'	System	20 Sep 2020 15:33:16
	System	20 Sep 2020 15:33:16

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:33:07', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cea068ec-b5bd-40ff-aaa1-83ab599bdff4' User entered 'None (0)'	System	20 Sep 2020 15:33:16
	System	20 Sep 2020 15:33:16

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:33:08', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cea068ec-b5bd-40ff-aaa1-83ab599bdff4' User entered 'None (0)'	System	20 Sep 2020 15:33:16
	System	20 Sep 2020 15:33:16

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:33:10', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cea068ec-b5bd-40ff-aaa1-83ab599bdff4' User entered 'None (0)'	System	20 Sep 2020 15:33:16
	System	20 Sep 2020 15:33:16

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:33:12', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cea068ec-b5bd-40ff-aaa1-83ab599bdff4'	System	20 Sep 2020 15:33:16
User entered 'No (N)'	System	20 Sep 2020 15:33:16



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-20T11:33:13', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cea068ec-b5bd-40ff-aaa1-83ab599bdff4' User entered '20 Sep 2020 11:33'	System	20 Sep 2020 15:33:16
	System	20 Sep 2020 15:33:16

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 3'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:43:06', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '6e05ca3f-011d-4ab8-b663-6bd1fcdc85d5' User entered 'None (0)'	System	21 Sep 2020 11:43:24
	System	21 Sep 2020 11:43:24

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:43:09', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '6e05ca3f-011d-4ab8-b663-6bd1fcdc85d5' User entered 'None (0)'	System	21 Sep 2020 11:43:24
	System	21 Sep 2020 11:43:24

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:43:10', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '6e05ca3f-011d-4ab8-b663-6bd1fcdc85d5' User entered 'None (0)'	System	21 Sep 2020 11:43:24
	System	21 Sep 2020 11:43:24

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:43:12', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '6e05ca3f-011d-4ab8-b663-6bd1fcdc85d5' User entered 'None (0)'	System	21 Sep 2020 11:43:24
	System	21 Sep 2020 11:43:24



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:43:14', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '6e05ca3f-011d-4ab8-b663-6bd1fc85d5' User entered 'None (0)'	System	21 Sep 2020 11:43:24
	System	21 Sep 2020 11:43:24

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:43:15', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '6e05ca3f-011d-4ab8-b663-6bd1fcdc85d5' User entered 'None (0)'	System	21 Sep 2020 11:43:24
	System	21 Sep 2020 11:43:24

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:43:18', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '6e05ca3f-011d-4ab8-b663-6bd1fcdc85d5' User entered 'No (N)'	System	21 Sep 2020 11:43:24
	System	21 Sep 2020 11:43:24

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-21T07:43:20', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '6e05ca3f-011d-4ab8-b663-6bd1fcdc85d5' User entered '21 Sep 2020 07:43'	System	21 Sep 2020 11:43:24
	System	21 Sep 2020 11:43:24

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 4'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:58:28', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e0bd3db9-24dd-478d-9c70-675a38840c6b' User entered 'None (0)'	System	22 Sep 2020 12:58:41
	System	22 Sep 2020 12:58:41



US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:58:29', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e0bd3db9-24dd-478d-9c70-675a38840c6b' User entered 'None (0)'	System	22 Sep 2020 12:58:41
	System	22 Sep 2020 12:58:41

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:58:31', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e0bd3db9-24dd-478d-9c70-675a38840c6b' User entered 'None (0)'	System	22 Sep 2020 12:58:41
	System	22 Sep 2020 12:58:41

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:58:32', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e0bd3db9-24dd-478d-9c70-675a38840c6b' User entered 'None (0)'	System	22 Sep 2020 12:58:41
	System	22 Sep 2020 12:58:41

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:58:34', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e0bd3db9-24dd-478d-9c70-675a38840c6b' User entered 'None (0)'	System	22 Sep 2020 12:58:41
	System	22 Sep 2020 12:58:41

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:58:35', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e0bd3db9-24dd-478d-9c70-675a38840c6b' User entered 'None (0)'	System	22 Sep 2020 12:58:41
	System	22 Sep 2020 12:58:41

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:58:37', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e0bd3db9-24dd-478d-9c70-675a38840c6b' User entered 'No (N)'	System	22 Sep 2020 12:58:41
	System	22 Sep 2020 12:58:41

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-22T08:58:39', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e0bd3db9-24dd-478d-9c70-675a38840c6b' User entered '22 Sep 2020 08:58'	System	22 Sep 2020 12:58:41
	System	22 Sep 2020 12:58:41

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 18:22:03



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 5'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:15:39', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '64667f41-7170-4b57-b834-aea4cb8f2788' User entered 'None (0)'	System	23 Sep 2020 11:15:54
	System	23 Sep 2020 11:15:54

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:15:40', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '64667f41-7170-4b57-b834-aea4cb8f2788' User entered 'None (0)'	System	23 Sep 2020 11:15:54
	System	23 Sep 2020 11:15:54

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:15:42', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '64667f41-7170-4b57-b834-aea4cb8f2788' User entered 'None (0)'	System	23 Sep 2020 11:15:54
	System	23 Sep 2020 11:15:54

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:15:44', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '64667f41-7170-4b57-b834-aea4cb8f2788' User entered 'None (0)'	System	23 Sep 2020 11:15:54
	System	23 Sep 2020 11:15:54

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:15:45', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '64667f41-7170-4b57-b834-aea4cb8f2788' User entered 'None (0)'	System	23 Sep 2020 11:15:54
	System	23 Sep 2020 11:15:54

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:15:47', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '64667f41-7170-4b57-b834-aea4cb8f2788' User entered 'None (0)'	System	23 Sep 2020 11:15:54
	System	23 Sep 2020 11:15:54



US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:15:48', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '64667f41-7170-4b57-b834-aea4cb8f2788' User entered 'No (N)'	System	23 Sep 2020 11:15:54
	System	23 Sep 2020 11:15:54

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-23T07:15:50', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '64667f41-7170-4b57-b834-aea4cb8f2788' User entered '23 Sep 2020 07:15'	System	23 Sep 2020 11:15:54
	System	23 Sep 2020 11:15:54

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 6'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:11', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '331c60d5-9324-42e7-93b6-5f4fdf0b9dd4' User entered 'None (0)'	System	24 Sep 2020 13:06:25
	System	24 Sep 2020 13:06:25

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:12', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '331c60d5-9324-42e7-93b6-5f4fdf0b9dd4' User entered 'None (0)'	System	24 Sep 2020 13:06:25
	System	24 Sep 2020 13:06:25

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:14', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '331c60d5-9324-42e7-93b6-5f4fdf0b9dd4' User entered 'None (0)'	System	24 Sep 2020 13:06:25
	System	24 Sep 2020 13:06:25



US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:15', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '331c60d5-9324-42e7-93b6-5f4fdf0b9dd4' User entered 'None (0)'	System	24 Sep 2020 13:06:25
	System	24 Sep 2020 13:06:25

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:16', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '331c60d5-9324-42e7-93b6-5f4fdf0b9dd4' User entered 'None (0)'	System	24 Sep 2020 13:06:25
	System	24 Sep 2020 13:06:25

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:18', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '331c60d5-9324-42e7-93b6-5f4fdf0b9dd4' User entered 'None (0)'	System	24 Sep 2020 13:06:25
	System	24 Sep 2020 13:06:25

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:19', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '331c60d5-9324-42e7-93b6-5f4fdf0b9dd4' User entered 'No (N)'	System	24 Sep 2020 13:06:25
	System	24 Sep 2020 13:06:25

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-24T09:06:21', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '331c60d5-9324-42e7-93b6-5f4fdf0b9dd4' User entered '24 Sep 2020 09:06'	System	24 Sep 2020 13:06:25
	System	24 Sep 2020 13:06:25

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	18 Sep 2020 18:22:03
User entered 'Day 7'	System	18 Sep 2020 18:22:03



US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:11

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:54:51', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '294a2abb-2e43-47a0-b578-a3fbdf6c95f5' User entered 'None (0)'	System	25 Sep 2020 13:55:07
	System	25 Sep 2020 13:55:07

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:54:52', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '294a2abb-2e43-47a0-b578-a3fbdf6c95f5' User entered 'None (0)'	System	25 Sep 2020 13:55:07
	System	25 Sep 2020 13:55:07

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:11

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:54:53', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '294a2abb-2e43-47a0-b578-a3fbdf6c95f5' User entered 'None (0)'	System	25 Sep 2020 13:55:07
	System	25 Sep 2020 13:55:07

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:11

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:54:54', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '294a2abb-2e43-47a0-b578-a3fbdf6c95f5' User entered 'None (0)'	System	25 Sep 2020 13:55:07
	System	25 Sep 2020 13:55:07

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:54:56', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '294a2abb-2e43-47a0-b578-a3fbdf6c95f5' User entered 'None (0)'	System	25 Sep 2020 13:55:07
	System	25 Sep 2020 13:55:07

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:54:57', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '294a2abb-2e43-47a0-b578-a3bdf6c95f5' User entered 'None (0)'	System	25 Sep 2020 13:55:07
	System	25 Sep 2020 13:55:07

US3522200

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:56:11

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)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:54:59', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '294a2abb-2e43-47a0-b578-a3fbdf6c95f5' User entered 'No (N)'	System	25 Sep 2020 13:55:07
	System	25 Sep 2020 13:55:07

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-09-25T09:55:02', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '294a2abb-2e43-47a0-b578-a3fbdf6c95f5' User entered '25 Sep 2020 09:55'	System	25 Sep 2020 13:55:07
	System	25 Sep 2020 13:55:07



**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 07:56:11**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 18:22:03

**US3522200**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 14:24:16

**US3522200**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '25 Sep 2020'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 14:24:16

US3522200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 14:24:16

US3522200

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 14:24:16

US3522200

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 14:24:21

**US3522200**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'I'	System	25 Sep 2020 14:24:21



**US3522200**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:48:03

**US3522200**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:48:03

US3522200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:48:03

US3522200

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'No ongoing AE reported, no new illness; no changes in health status, medications, Covid-19 exposure or pregnancy risk. Receiving flu vaccine today.'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:48:03

US3522200

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:48:07

**US3522200**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'I'	System	02 Oct 2020 17:48:07

**US3522200**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:09:22

**US3522200**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:09:22



US3522200

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:09:22

US3522200

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk'	(b) (4) (b) (4), (b) (6)	09 Oct 2020 15:09:22

**US3522200**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:51
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:57:36

**US3522200**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'I'	System	23 Oct 2020 12:57:36

**US3522200**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:57:49

**US3522200**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:57:49

US3522200

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:57:49

**US3522200**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered 'VISIT3'	System	23 Oct 2020 12:57:49



US3522200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:58:32

US3522200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:58:32

**US3522200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '08:40'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:58:32

**US3522200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered '23 Oct 2020 08:40'	System	23 Oct 2020 12:58:32

US3522200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '96.8' F	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:58:32

US3522200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:58:32

US3522200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:58:32

**US3522200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '90'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:58:32



**US3522200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered 'bpm'	System	23 Oct 2020 12:58:32

US3522200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '16'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:58:32

US3522200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered 'breaths/min'	System	23 Oct 2020 12:58:32

US3522200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User closed query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 06:58:36
Query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' answered with 'NCS' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	29 Oct 2020 12:22:32
User opened query 'Per CDM: Systolic blood pressure is out of range per protocol. Please indicate if CS or NCS and report as AE, if appropriate' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 10:22:49
User entered '158'	(b) (4), (b) (6)	23 Oct 2020 12:58:32

**US3522200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered 'mmHg'	System	23 Oct 2020 12:58:32

US3522200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '96'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:58:32

**US3522200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered 'mmHg'	System	23 Oct 2020 12:58:32

US3522200

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59



**US3522200**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59

US3522200

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:58:47

**US3522200**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:11**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:58:47

US3522200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:59:03

US3522200

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:59:03

**US3522200**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:11**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered '08:45'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:59:03

**US3522200**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered '23 Oct 2020 08:45'	System	23 Oct 2020 12:59:03

US3522200

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:16:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 12:59:09



**US3522200**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:59
User entered 'I'	System	23 Oct 2020 12:59:09

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 64'	System	19 Aug 2020 13:39:34

US3522200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-10-22T18:02:18', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e837d6e1-338f-4c80-a5be-eee5ecd0f64b' User entered 'No (N)'	System	22 Oct 2020 22:02:28
	System	22 Oct 2020 22:02:28

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-10-22T18:02:22', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e837d6e1-338f-4c80-a5be-eee5ecd0f64b'	System	22 Oct 2020 22:02:28
User entered 'No (N)'	System	22 Oct 2020 22:02:28

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-10-22T18:02:25', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e837d6e1-338f-4c80-a5be-eee5ecd0f64b' User entered '22 Oct 2020 18:02:25'	System	22 Oct 2020 22:02:28
	System	22 Oct 2020 22:02:28

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 13:39:34

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 13:39:34

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 71'	System	19 Aug 2020 13:39:34



US3522200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-10-28T12:10:50', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3970302f-4cfb-4177-8e60-27fcf0cf527e' User entered 'No (N)'	System	28 Oct 2020 16:10:58
	System	28 Oct 2020 16:10:58

US3522200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-10-28T12:10:53', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3970302f-4cfb-4177-8e60-27fcf0cf527e'	System	28 Oct 2020 16:10:58
User entered 'No (N)'	System	28 Oct 2020 16:10:58

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-10-28T12:10:56', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3970302f-4cfb-4177-8e60-27fcf0cf527e' User entered '28 Oct 2020 12:10:56'	System	28 Oct 2020 16:10:58
	System	28 Oct 2020 16:10:58

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 13:39:34

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 13:39:34

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 78'	System	19 Aug 2020 13:39:34

US3522200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-11-04T12:00:38', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e434da6e-52fa-46e8-8406-73150e579d78' User entered 'No (N)'	System	04 Nov 2020 17:01:35
	System	04 Nov 2020 17:01:35

US3522200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-11-04T12:00:42', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e434da6e-52fa-46e8-8406-73150e579d78'	System	04 Nov 2020 17:01:35
User entered 'No (N)'	System	04 Nov 2020 17:01:35



**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-11-04T12:00:44', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e434da6e-52fa-46e8-8406-73150e579d78' User entered '04 Nov 2020 12:00:44'	System	04 Nov 2020 17:01:35
	System	04 Nov 2020 17:01:35

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 13:39:34

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 13:39:34

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered 'Day 92'	System	19 Aug 2020 13:39:34

US3522200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-11-18T12:06:40', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '8b20ece9-1c0c-4269-8f45-e56e6bfc75db' User entered 'No (N)'	System	18 Nov 2020 17:06:52
	System	18 Nov 2020 17:06:52

US3522200

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-11-18T12:06:44', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '8b20ece9-1c0c-4269-8f45-e56e6bfc75db'	System	18 Nov 2020 17:06:52
User entered 'No (N)'	System	18 Nov 2020 17:06:52

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-11-18T12:06:47', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '8b20ece9-1c0c-4269-8f45-e56e6bfc75db' User entered '18 Nov 2020 12:06:47'	System	18 Nov 2020 17:06:52
	System	18 Nov 2020 17:06:52

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 13:39:34



**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 10:45:45
Data entry locked.	System	19 Aug 2020 13:39:34
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 13:39:34

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-11-24T09:56:05', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e358b874-22e8-4910-af7a-6be1b462db07'	System	24 Nov 2020 14:56:12
User entered 'No (N)'	System	24 Nov 2020 14:56:12

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-11-24T09:56:07', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e358b874-22e8-4910-af7a-6be1b462db07'	System	24 Nov 2020 14:56:12
User entered 'No (N)'	System	24 Nov 2020 14:56:12

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-11-24T09:56:09', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'e358b874-22e8-4910-af7a-6be1b462db07' User entered '24 Nov 2020 09:56:09'	System	24 Nov 2020 14:56:12
	System	24 Nov 2020 14:56:12

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:42:26



**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-11-27T09:14:28', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '1fd5d9ae-5bb7-46fa-8619-942852b1dbce'	System	27 Nov 2020 14:14:36
User entered 'No (N)'	System	27 Nov 2020 14:14:36

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-11-27T09:14:30', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '1fd5d9ae-5bb7-46fa-8619-942852b1dbce' User entered 'No (N)'	System	27 Nov 2020 14:14:36

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-11-27T09:14:32', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '1fd5d9ae-5bb7-46fa-8619-942852b1dbce' User entered '27 Nov 2020 09:14:32'	System	27 Nov 2020 14:14:36
	System	27 Nov 2020 14:14:36

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:42:26

US3522200

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:11

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 13:25:04
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'see sae papillary thyroid cancer' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 18:53:25
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	06 Mar 2021 13:03:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-04T14:17:59', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ad3d3287-bcfc-459d-bced-fe4eccd2620f'	System	04 Dec 2020 19:19:10
User entered 'Yes (Y)'	System	04 Dec 2020 19:19:10

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-04T14:18:11', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ad3d3287-bcfc-459d-bced-fe4eccd2620f' User entered 'Yes (Y)'	System	04 Dec 2020 19:19:10
	System	04 Dec 2020 19:19:10



**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Please 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-04T14:18:21', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ad3d3287-bcfc-459d-bced-fe4eccd2620f'	System	04 Dec 2020 19:19:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Dec 2020 19:19:10

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-04T14:18:31', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ad3d3287-bcfc-459d-bced-fe4eccd2620f' User entered 'No (N)'	System	04 Dec 2020 19:19:10
	System	04 Dec 2020 19:19:10

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-04T14:18:42', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ad3d3287-bcfc-459d-bced-fe4eccd2620f' User entered 'Yes (Y)'	System	04 Dec 2020 19:19:10
	System	04 Dec 2020 19:19:10

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Please 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-04T14:18:46', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ad3d3287-bcfc-459d-bced-fe4eccd2620f'	System	04 Dec 2020 19:19:10
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Dec 2020 19:19:10

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-04T14:18:57', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ad3d3287-bcfc-459d-bced-fe4eccd2620f' User entered '04 Dec 2020 14:18:57'	System	04 Dec 2020 19:19:10
	System	04 Dec 2020 19:19:10

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:42:26



**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-11T10:04:35', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3689e682-57fe-4c6e-8e91-c2379cf50c72'	System	11 Dec 2020 15:04:43
User entered 'No (N)'	System	11 Dec 2020 15:04:43

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-11T10:04:38', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3689e682-57fe-4c6e-8e91-c2379cf50c72'	System	11 Dec 2020 15:04:43
User entered 'No (N)'	System	11 Dec 2020 15:04:43

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-11T10:04:41', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3689e682-57fe-4c6e-8e91-c2379cf50c72' User entered '11 Dec 2020 10:04:41'	System	11 Dec 2020 15:04:43
	System	11 Dec 2020 15:04:43

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-18T13:29:33', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '7ad710fd-4725-4653-a32a-fbd06a11db4d' User entered 'No (N)'	System	18 Dec 2020 18:29:41
	System	18 Dec 2020 18:29:41

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-18T13:29:34', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '7ad710fd-4725-4653-a32a-fbd06a11db4d' User entered 'No (N)'	System	18 Dec 2020 18:29:41
	System	18 Dec 2020 18:29:41



**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-18T13:29:36', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '7ad710fd-4725-4653-a32a-fbd06a11db4d' User entered '18 Dec 2020 13:29:36'	System	18 Dec 2020 18:29:41
	System	18 Dec 2020 18:29:41

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-25T09:10:34', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '19ab3ec3-0c4b-44d6-86cd-b5ac8d1aa180'	System	25 Dec 2020 14:10:44
User entered 'No (N)'	System	25 Dec 2020 14:10:44

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-25T09:10:38', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '19ab3ec3-0c4b-44d6-86cd-b5ac8d1aa180'	System	25 Dec 2020 14:10:44
User entered 'No (N)'	System	25 Dec 2020 14:10:44

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2020-12-25T09:10:41', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '19ab3ec3-0c4b-44d6-86cd-b5ac8d1aa180' User entered '25 Dec 2020 09:10:41'	System	25 Dec 2020 14:10:44
	System	25 Dec 2020 14:10:44

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 22:42:26



**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-01-01T00:01:32', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'd0b0dde1-046c-412c-8d0d-50a5d5242c25'	System	01 Jan 2021 05:01:47
User entered 'No (N)'	System	01 Jan 2021 05:01:47

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-01-01T00:01:39', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'd0b0dde1-046c-412c-8d0d-50a5d5242c25'	System	01 Jan 2021 05:01:47
User entered 'No (N)'	System	01 Jan 2021 05:01:47

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-01-01T00:01:42', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'd0b0dde1-046c-412c-8d0d-50a5d5242c25'	System	01 Jan 2021 05:01:47
User entered '01 Jan 2021 00:01:42'	System	01 Jan 2021 05:01:47

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:42:26



**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-01-10T12:04:10', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '9142ad4a-9717-4a6f-aad1-c2ab896ba911'	System	10 Jan 2021 17:04:18
User entered 'No (N)'	System	10 Jan 2021 17:04:18

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-01-10T12:04:12', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '9142ad4a-9717-4a6f-aad1-c2ab896ba911'	System	10 Jan 2021 17:04:18
User entered 'No (N)'	System	10 Jan 2021 17:04:18

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-01-10T12:04:14', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '9142ad4a-9717-4a6f-aad1-c2ab896ba911' User entered '10 Jan 2021 12:04:14'	System	10 Jan 2021 17:04:18
	System	10 Jan 2021 17:04:18

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-01-18T17:59:21', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cb25b9dd-dee8-424e-85cd-de9c395f46d5'	System	18 Jan 2021 22:59:33
User entered 'No (N)'	System	18 Jan 2021 22:59:33

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-01-18T17:59:23', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cb25b9dd-dee8-424e-85cd-de9c395f46d5'	System	18 Jan 2021 22:59:33
User entered 'No (N)'	System	18 Jan 2021 22:59:33



**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-01-18T17:59:27', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'cb25b9dd-dee8-424e-85cd-de9c395f46d5'	System	18 Jan 2021 22:59:33
User entered '18 Jan 2021 17:59:27'	System	18 Jan 2021 22:59:33

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-01-24T12:03:47', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b3670ead-d2f2-4f17-8635-e7585adc2169' User entered 'No (N)'	System	24 Jan 2021 17:05:32

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-01-24T12:03:48', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b3670ead-d2f2-4f17-8635-e7585adc2169'	System	24 Jan 2021 17:05:32
User entered 'No (N)'	System	24 Jan 2021 17:05:32

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-01-24T12:03:51', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b3670ead-d2f2-4f17-8635-e7585adc2169' User entered '24 Jan 2021 12:03:51'	System	24 Jan 2021 17:05:32

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 22:42:26



**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-01T06:54:14', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3ab3b061-e453-42a1-bdb8-18ea9786912c'	System	01 Feb 2021 11:54:22
User entered 'No (N)'	System	01 Feb 2021 11:54:22

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-01T06:54:16', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3ab3b061-e453-42a1-bdb8-18ea9786912c' User entered 'No (N)'	System	01 Feb 2021 11:54:22
	System	01 Feb 2021 11:54:22

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-01T06:54:18', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '3ab3b061-e453-42a1-bdb8-18ea9786912c' User entered '01 Feb 2021 06:54:18'	System	01 Feb 2021 11:54:22

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:42:26



**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-05T08:07:36', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ddec7127-34c9-4b00-9965-ac0ccac266e8' User entered 'No (N)'	System	05 Feb 2021 13:07:45
	System	05 Feb 2021 13:07:45

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-05T08:07:39', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ddec7127-34c9-4b00-9965-ac0ccac266e8' User entered 'No (N)'	System	05 Feb 2021 13:07:45
	System	05 Feb 2021 13:07:45

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-05T08:07:41', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'ddec7127-34c9-4b00-9965-ac0ccac266e8' User entered '05 Feb 2021 08:07:41'	System	05 Feb 2021 13:07:45
	System	05 Feb 2021 13:07:45

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-14T12:22:15', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '6879c7fc-e691-4802-828a-923fee00ca6d' User entered 'No (N)'	System	14 Feb 2021 17:22:24
	System	14 Feb 2021 17:22:24

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-14T12:22:17', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '6879c7fc-e691-4802-828a-923fee00ca6d' User entered 'No (N)'	System	14 Feb 2021 17:22:24
	System	14 Feb 2021 17:22:24



**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-14T12:22:22', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '6879c7fc-e691-4802-828a-923fee00ca6d' User entered '14 Feb 2021 12:22:22'	System	14 Feb 2021 17:22:24
	System	14 Feb 2021 17:22:24

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:42:26

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-19T06:53:43', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b2ef89e4-1e2d-4dae-b5a9-aaf1fe697916'	System	19 Feb 2021 11:53:51
User entered 'No (N)'	System	19 Feb 2021 11:53:51

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-19T06:53:45', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b2ef89e4-1e2d-4dae-b5a9-aaf1fe697916' User entered 'No (N)'	System	19 Feb 2021 11:53:51

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-19T06:53:47', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'b2ef89e4-1e2d-4dae-b5a9-aaf1fe697916' User entered '19 Feb 2021 06:53:47'	System	19 Feb 2021 11:53:51
	System	19 Feb 2021 11:53:51

**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 22:42:26



**US3522200**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-26T14:08:55-06:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '4634a533-2607-4cc3-8bb1-e70240f36b85' User entered 'No (N)'	System	26 Feb 2021 20:09:05
	System	26 Feb 2021 20:09:05

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-26T14:08:58-06:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '4634a533-2607-4cc3-8bb1-e70240f36b85'	System	26 Feb 2021 20:09:05
User entered 'No (N)'	System	26 Feb 2021 20:09:05

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-02-26T14:09:01-06:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '4634a533-2607-4cc3-8bb1-e70240f36b85' User entered '26 Feb 2021 20:09:01'	System	26 Feb 2021 20:09:05
	System	26 Feb 2021 20:09:05

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-03-07T12:22:08-05:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '59f58f33-635f-4c8a-a227-f3f44e4edcc1' User entered 'No (N)'	System	07 Mar 2021 17:22:13

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-03-07T12:22:10-05:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '59f58f33-635f-4c8a-a227-f3f44e4edcc1'	System	07 Mar 2021 17:22:13
User entered 'No (N)'	System	07 Mar 2021 17:22:13

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-03-07T12:22:11-05:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '59f58f33-635f-4c8a-a227-f3f44e4edcc1' User entered '07 Mar 2021 12:22:11'	System	07 Mar 2021 17:22:13
	System	07 Mar 2021 17:22:13

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-03-12T12:07:41-05:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '201da77a-497e-444d-b898-d073b6755235'	System	12 Mar 2021 17:11:24
User entered 'No (N)'	System	12 Mar 2021 17:11:24

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-03-12T12:07:43-05:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '201da77a-497e-444d-b898-d073b6755235'	System	12 Mar 2021 17:11:24
User entered 'No (N)'	System	12 Mar 2021 17:11:24



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-03-12T12:07:46-05:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '201da77a-497e-444d-b898-d073b6755235' User entered '12 Mar 2021 12:07:46'	System	12 Mar 2021 17:11:24
	System	12 Mar 2021 17:11:24

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-03-21T08:40:27-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '67280a21-2612-47b4-9e68-7fa352996d22'	System	21 Mar 2021 12:40:34
User entered 'No (N)'	System	21 Mar 2021 12:40:34

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-03-21T08:40:29-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '67280a21-2612-47b4-9e68-7fa352996d22'	System	21 Mar 2021 12:40:34
User entered 'No (N)'	System	21 Mar 2021 12:40:34

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-03-21T08:40:31-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '67280a21-2612-47b4-9e68-7fa352996d22'	System	21 Mar 2021 12:40:34
User entered '21 Mar 2021 08:40:31'	System	21 Mar 2021 12:40:34

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-03-28T09:35:23-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '47b63077-8547-4ce3-8c5e-81d84f14957c'	System	28 Mar 2021 13:35:30
User entered 'No (N)'	System	28 Mar 2021 13:35:30

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-03-28T09:35:24-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '47b63077-8547-4ce3-8c5e-81d84f14957c'	System	28 Mar 2021 13:35:30
User entered 'No (N)'	System	28 Mar 2021 13:35:30

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-03-28T09:35:26-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '47b63077-8547-4ce3-8c5e-81d84f14957c' User entered '28 Mar 2021 09:35:26'	System	28 Mar 2021 13:35:30
	System	28 Mar 2021 13:35:30

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-02T06:16:41-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '14abb694-b8a3-42e4-8561-14d4fcfc434b' User entered 'No (N)'	System	02 Apr 2021 10:16:51
	System	02 Apr 2021 10:16:51

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-02T06:16:43-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '14abb694-b8a3-42e4-8561-14d4fcfc434b'	System	02 Apr 2021 10:16:51
User entered 'No (N)'	System	02 Apr 2021 10:16:51

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-02T06:16:46-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '14abb694-b8a3-42e4-8561-14d4fcfc434b'	System	02 Apr 2021 10:16:51
User entered '02 Apr 2021 06:16:46'	System	02 Apr 2021 10:16:51

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-09T13:08:36-05:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '8084b8b8-2bbd-4276-9f60-18bfd8c88871'	System	09 Apr 2021 18:08:46
User entered 'No (N)'	System	09 Apr 2021 18:08:46

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-09T13:08:37-05:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '8084b8b8-2bbd-4276-9f60-18bfd8c88871'	System	09 Apr 2021 18:08:46
User entered 'No (N)'	System	09 Apr 2021 18:08:46



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-09T13:08:40-05:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '8084b8b8-2bbd-4276-9f60-18bfd8c88871'	System	09 Apr 2021 18:08:46
User entered '09 Apr 2021 13:08:40'	System	09 Apr 2021 18:08:46

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-20T12:00:38-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '603197fd-60e4-462f-9a7a-d438e1caf978'	System	20 Apr 2021 16:01:25
User entered 'No (N)'	System	20 Apr 2021 16:01:25

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-20T12:00:39-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '603197fd-60e4-462f-9a7a-d438e1caf978'	System	20 Apr 2021 16:01:25
User entered 'No (N)'	System	20 Apr 2021 16:01:25

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-20T12:00:41-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '603197fd-60e4-462f-9a7a-d438e1caf978'	System	20 Apr 2021 16:01:25
User entered '20 Apr 2021 12:00:41'	System	20 Apr 2021 16:01:25

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-25T12:02:04-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '2524b4c3-2872-4b27-87c5-e261a401fbd2'	System	25 Apr 2021 16:06:23
User entered 'No (N)'	System	25 Apr 2021 16:06:23

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-25T12:02:05-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '2524b4c3-2872-4b27-87c5-e261a401fbd2'	System	25 Apr 2021 16:06:23
User entered 'No (N)'	System	25 Apr 2021 16:06:23

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-25T12:02:07-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '2524b4c3-2872-4b27-87c5-e261a401fbd2'	System	25 Apr 2021 16:06:23
User entered '25 Apr 2021 12:02:07'	System	25 Apr 2021 16:06:23

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-30T06:06:02-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'de5e1f37-224b-43e8-9d98-5d1b17491448'	System	30 Apr 2021 10:06:12
User entered 'No (N)'	System	30 Apr 2021 10:06:12

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

Have you been exposed to someone with 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 (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-30T06:06:05-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'de5e1f37-224b-43e8-9d98-5d1b17491448'	System	30 Apr 2021 10:06:12
User entered 'No (N)'	System	30 Apr 2021 10:06:12

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-04-30T06:06:09-04:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: 'de5e1f37-224b-43e8-9d98-5d1b17491448'	System	30 Apr 2021 10:06:12
User entered '30 Apr 2021 06:06:09'	System	30 Apr 2021 10:06:12

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:42:26



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 22:42:26

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 22:42:26



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:42:26



**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 22:42:26



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 22:42:26



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 22:42:26

**US3522200**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:56:11**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:42:26
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 22:42:26

US3522200

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:56:11

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:01:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-03-07T12:22:17-05:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '0c1772ef-529e-459c-86cc-0e0b3c2f1dc9'	System	07 Mar 2021 17:22:23
User entered 'No (N)'	System	07 Mar 2021 17:22:23

**US3522200**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:01:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D091F7EF-F4F7-43E7-82BE-A2523546DE8E)', Time: '2021-03-07T12:22:19-05:00', User OID: 'PatientReportedOutcome (US3522200)', ODM File OID: '0c1772ef-529e-459c-86cc-0e0b3c2f1dc9' User entered '07 Mar 2021 12:22:19'	System	07 Mar 2021 17:22:23
	System	07 Mar 2021 17:22:23

**US3522200**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:47:27

**US3522200**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:47:27



**US3522200**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:47:27

US3522200

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:47:27

**US3522200**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:47:31

**US3522200**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:46:53
User entered 'I'	System	13 Nov 2020 17:47:31

**US3522200**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	17 Dec 2020 18:39:41

**US3522200**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '17 Dec 2020'	Yaman Ahmed (b) (4)	17 Dec 2020 18:39:41

**US3522200**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	17 Dec 2020 18:39:41

US3522200

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'PAPILLARY THYROID IS STAGE 1 AND WILL SEE SPECIALIST AT END OF DECEMBER 2020 IN PREPARATION FOR SURGERY. ON 05 DEC 2020, TOPIRAMATE WAS STOPPED AND SWITCHED TO PROPRANOLOL. NO COVID-19 EXPOSURE'	Yaman Ahmed (b) (4)	17 Dec 2020 18:42:11
reason for change: Data Entry Error		
User entered 'Papillary Thyroid cancer is stage 1 (will keep grade as Grade 2) and she will be seeing a specialist at the end of December 2020 in preparation for surgery. On 05 Dec 2020, Topiramate was stopped because it was interfering with her birth control so she was switched to Propranolol 40 mg twice daily on 05 Dec 2020. No Covid-19 exposure' (non-conformant).	Yaman Ahmed (b) (4)	17 Dec 2020 18:39:41



**US3522200**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	17 Dec 2020 18:42:17

**US3522200**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User entered 'I'	System	17 Dec 2020 18:42:17

**US3522200**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:04:45

**US3522200**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '18 Jan 2021'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:04:45

**US3522200**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:04:45

US3522200

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered "'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'"	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:04:45

**US3522200**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Jan 2021 16:04:49

**US3522200**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User entered 'I'	System	18 Jan 2021 16:04:49



**US3522200**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:14:10

US3522200

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '16 Feb 2021' reason for change: New Information	(b) (4)	
	Yaman Ahmed (b) (4)	16 Feb 2021 21:14:41
User entered '15 Feb 2021'	(b) (4), (b) (6)	15 Feb 2021 19:14:10

US3522200

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: New Information	Yaman Ahmed (b) (4)	16 Feb 2021 21:14:41
User entered 'Contact Not Made (CONTACT NOT	(b) (4)	
MADE)'	(b) (4), (b) (6)	15 Feb 2021 19:14:10

US3522200

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'POST TOTAL THYROIDECTOMY, SHE UNDERWENT RADIOACTIVE IODINE TREATMENT FOR TALL CELL VARIANT PAPILLARY THYROID CANCER; LIOTHYRONINE WAS INCREASED FROM 50 25 MICROGRAM TO 100 MICROGRAMS ON 13 FEB 2021.' reason for change: New Information	Yaman Ahmed (b) (4)	16 Feb 2021 21:15:09
User entered 'post total thyroidectomy, she underwent radioactive iodine treatment on 11 Feb 2021 for tall cell variant papillary thyroid cancer; Liothyronine was increased from 50 25 microgram to 100 micrograms on 13 Feb 2021.' (non-conformant).	Yaman Ahmed (b) (4)	16 Feb 2021 21:14:41
User entered 'vm'	(b) (4), (b) (6)	15 Feb 2021 19:14:10

**US3522200**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:14:43

**US3522200**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User entered 'I'	System	15 Feb 2021 19:14:43

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:06:55

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:06:55



**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:06:55

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User entered 'VISIT4'	System	26 Mar 2021 15:06:55

US3522200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 16:59:49

US3522200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '26 Mar 2021'	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 16:59:49

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '10:50'	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 16:59:49

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User entered '26 Mar 2021 10:50'	System	30 Mar 2021 16:59:49

US3522200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '98.0' F	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 16:59:49

US3522200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'Other (Other)'	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 16:59:49



US3522200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'TEMPORAL' reason for change: Data Entry Error	(b) (4)	
	Yaman Ahmed (b) (4)	30 Mar 2021 17:00:36
User entered 'infrared'	(b) (4)	
	Yaman Ahmed (b) (4)	30 Mar 2021 16:59:49
	(b) (4)	

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '72'	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 16:59:49

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User entered 'bpm'	System	30 Mar 2021 16:59:49

US3522200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '14'	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 16:59:49

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User entered 'breaths/min'	System	30 Mar 2021 16:59:49

US3522200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '129'	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 16:59:49

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User entered 'mmHg'	System	30 Mar 2021 16:59:49

US3522200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '82'	(b) (4) Yaman Ahmed (b) (4)	30 Mar 2021 16:59:49



US3522200

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User entered 'mmHg'	System	30 Mar 2021 16:59:49

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11

US3522200

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:07:05

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:11**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:07:05

US3522200

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:07:22

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:11**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:07:22

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:11**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '10:58'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:07:22



**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User entered '26 Mar 2021 10:58'	System	26 Mar 2021 15:07:22

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:07:29

**US3522200**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:17:11
User entered 'I'	System	26 Mar 2021 15:07:29

**US3522200**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:01:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:34

**US3522200**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:01:47
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:34

**US3522200**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:01:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:34

US3522200

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:01:47
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:34

US3522200

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:01:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:44



**US3522200**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 16:20:44

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:07:32

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '22 Jan 2021'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:07:32

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:56:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Clinic (Clinic)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:07:32

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 20:07:32

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:56:11**

**Date of updated informed consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '22 Jan 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:07:45

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:56:11**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
User entered '0'	(b) (4) Sharon Mathys (b) (4)	17 Mar 2021 11:31:51
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 05:42:51

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:56:11**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:07:45



**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:56:11**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Sharon Mathys (b) (4)	17 Mar 2021 11:31:51
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 05:42:51

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:56:11

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '22 Jan 2021'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:07:45

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:56:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Placebo (Placebo)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:07:45

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:56:11**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Placebo (Placebo)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:07:45

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:56:11**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Placebo (Placebo)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:07:45

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 07:56:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:07:45

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:56:11**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered '1'	System	22 Jan 2021 20:07:45

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'I'	System	22 Jan 2021 20:07:45



US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '67' in	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:56:11**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '135' lb	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:56:11**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered '21.18820'	System	22 Jan 2021 20:09:23
DataPoint set to visible.	System	22 Jan 2021 20:07:45

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:11

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '67' in	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:56:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '135' lb	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:56:11**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered '21.18820'	System	22 Jan 2021 20:09:23
DataPoint set to visible.	System	22 Jan 2021 20:07:45

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User accepted default value 'Pre-Dose (PREDOSE)'	Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23



US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '22 Jan 2021'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '14:20'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered '22 Jan 2021 14:20'	System	22 Jan 2021 20:09:23

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '98.5' F	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Other (Other)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'temporal'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '62'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'bpm'	System	22 Jan 2021 20:09:23



US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '20'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'breaths/min'	System	22 Jan 2021 20:09:23

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '138'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'mmHg'	System	22 Jan 2021 20:09:23

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '62'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'mmHg'	System	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:56:11**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '67' in	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:56:11**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '135' lb	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23



**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 07:56:11**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered '21.18820'	System	22 Jan 2021 20:09:23
DataPoint set to visible.	System	22 Jan 2021 20:07:45

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User accepted default value 'Post-Dose (POSTDOSE)'	Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '22 Jan 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '15:00'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered '22 Jan 2021 15:00'	System	22 Jan 2021 20:09:23

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '98.1' F	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:09:23
	(b) (4)	

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Other (Other)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23



US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'temporal'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '69'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'bpm'	System	22 Jan 2021 20:09:23

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '20'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'breaths/min'	System	22 Jan 2021 20:09:23

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '124'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'mmHg'	System	22 Jan 2021 20:09:23

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '72'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:09:23



**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'mmHg'	System	22 Jan 2021 20:09:23

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:11**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:37

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:56:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '22 Jan 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:37

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 10 Jun 2021 07:56:11

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.'" (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 10:29:30
Query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.'" answered with 'Participant declined due to recent test prior to radiation for thyroid CA' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 13:40:46
User opened query 'Per CDM: Childbearing potential noted as "yes" yet pregnancy test not completed. Kindly review and update else clarify.'" (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 04:39:36
User entered 'No (N)'	Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:09:48

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	Alayna Wilder (b) (4)	22 Jan 2021 20:09:48

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:09:48

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:09:48

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:09:48



**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:09:48

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:09:48

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered empty.	System	22 Jan 2021 20:09:48

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:10:05

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:11**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:10:05

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

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)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	Alayna Wilder (b) (4)	22 Jan 2021 20:10:05

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:11**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'mRNA-1273'	System	22 Jan 2021 20:10:05
DataPoint set to visible.	System	22 Jan 2021 20:07:45

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '22 Jan 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:10:05



US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '14:22'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:10:05

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:11**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered '22 Jan 2021 14:22'	System	22 Jan 2021 20:10:05

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:10:05

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'ONCE'	System	22 Jan 2021 20:10:05

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 20:10:05

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:10:31

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '22 Jan 2021'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:10:31

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:11**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '14:15'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:10:31



**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered '22 Jan 2021 14:15'	System	22 Jan 2021 20:10:31

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:56:11**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:10:44

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:56:11**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '22 Jan 2021'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:10:44

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:56:11**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '14:15'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:10:44

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 07:56:11**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered '22 Jan 2021 14:15'	System	22 Jan 2021 20:10:44

US3522200

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:56:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:10:51

**US3522200**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:08:50
User entered 'I'	System	22 Jan 2021 20:10:51

**US3522200**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:11:11



**US3522200**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:11:11

**US3522200**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:11:11

**US3522200**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:11:11

**US3522200**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:06
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Feb 2021 19:11:45

**US3522200**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:06
User entered 'I'	System	15 Feb 2021 19:11:45

**US3522200**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:06
User entered '1'	System	15 Feb 2021 19:11:45
DataPoint set to visible.	System	15 Feb 2021 19:11:45

**US3522200**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:06

**US3522200**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:06



**US3522200**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:06

**US3522200**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered 'OLD29'	System	19 Feb 2021 17:19:06

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '11:50'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered '19 Feb 2021 11:50'	System	19 Feb 2021 18:23:25

US3522200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:56:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25



**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '66'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered 'bpm'	System	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '14'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered 'breaths/min'	System	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '113'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered 'mmHg'	System	19 Feb 2021 18:23:25



**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '66'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered 'mmHg'	System	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '12:28'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered '19 Feb 2021 12:28'	System	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '99.3' F	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25



**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '59'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered 'bpm'	System	19 Feb 2021 18:23:25

US3522200

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:56:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '14'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered 'breaths/min'	System	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '108'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered 'mmHg'	System	19 Feb 2021 18:23:25



**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '77'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered 'mmHg'	System	19 Feb 2021 18:23:25

**US3522200**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:11**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:14

**US3522200**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:11**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:14

**US3522200**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:24

**US3522200**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:24

**US3522200**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Urine (URINE)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:24

**US3522200**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Negative (NEGATIVE)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:24



**US3522200**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:24

**US3522200**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:24

**US3522200**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:24

**US3522200**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered empty.	System	19 Feb 2021 17:19:24

US3522200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:36

**US3522200**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:11**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:36

US3522200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

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)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:36

**US3522200**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:11**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered 'mRNA-1273'	System	19 Feb 2021 17:19:36
DataPoint set to visible.	System	15 Feb 2021 19:11:45



US3522200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:36

**US3522200**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:11**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '11:58'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:36

**US3522200**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:11**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered '19 Feb 2021 11:58'	System	19 Feb 2021 17:19:36

US3522200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:36

US3522200

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:56:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered 'ONCE'	System	19 Feb 2021 17:19:36

**US3522200**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 07:56:11**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered 'INTRAMUSCULAR'	System	19 Feb 2021 17:19:36

**US3522200**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 17:19:40

**US3522200**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:08:05
User entered 'I'	System	19 Feb 2021 17:19:40



**US3522200**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)'	Alandra White (b) (4)	26 Feb 2021 20:09:19

**US3522200**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 07:56:11**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '26 Feb 2021'	Alandra White (b) (4)	26 Feb 2021 20:09:19

US3522200

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Alandra White (b) (4)	26 Feb 2021 20:12:48
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	Alandra White (b) (4)	26 Feb 2021 20:09:19
	(b) (4)	

US3522200

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:56:11

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:55
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.' reason for change: Data Entry Error	Alandra White (b) (4)	26 Feb 2021 20:12:48
User entered 'Call attempted with no answer, left voicemail.'	Alandra White (b) (4)	26 Feb 2021 20:09:19

**US3522200**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:55
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'Yes (Y)'	(b) (4) Sharon Mathys (b) (4) (b) (4)	10 Mar 2021 14:01:11

**US3522200**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 07:56:11**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:50:55
User entered 'I'	System	10 Mar 2021 14:01:11

**US3522200**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 15:05:14

**US3522200**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '26 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 15:05:14



**US3522200**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	26 Mar 2021 15:05:14

**US3522200**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 07:56:11**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User entered 'OLD57'	System	26 Mar 2021 15:05:14

**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:05:54

**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '26 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 15:05:54

**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '10:50'	(b) (4), (b) (6)	26 Mar 2021 15:05:54

**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User entered '26 Mar 2021 10:50'	System	26 Mar 2021 15:05:54

US3522200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '36.7' C	(b) (4), (b) (6)	26 Mar 2021 15:05:54

**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:05:54



**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'TEMPORAL'	(b) (4), (b) (6)	26 Mar 2021 15:05:54

**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '72'	(b) (4), (b) (6)	26 Mar 2021 15:05:54

**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User entered 'bpm'	System	26 Mar 2021 15:05:54

US3522200

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:56:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '14'	(b) (4), (b) (6)	26 Mar 2021 15:05:54

**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User entered 'breaths/min'	System	26 Mar 2021 15:05:54

**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '129'	(b) (4), (b) (6)	26 Mar 2021 15:05:54

**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User entered 'mmHg'	System	26 Mar 2021 15:05:54

**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '82'	(b) (4), (b) (6)	26 Mar 2021 15:05:54



**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User entered 'mmHg'	System	26 Mar 2021 15:05:54

**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54

**US3522200**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 07:56:11**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54

**US3522200**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:11**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 15:06:12

**US3522200**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 07:56:11**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '26 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 15:06:12

**US3522200**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:11**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 15:06:40

US3522200

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:56:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '26 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 15:06:40

**US3522200**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:11**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:34:28
User entered '10:58'	(b) (4), (b) (6)	26 Mar 2021 15:06:40



**US3522200**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 07:56:11**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:19:54
User entered '26 Mar 2021 10:58'	System	26 Mar 2021 15:06:40

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 07:56:11**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:47:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 19:48:00

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:54:45
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:16
User entered	System	05 Dec 2020 18:42:10
'USA-US131-2020-mRNA-1273-P301000012'		
User entered 'New'	(b) (4), (b) (6)	05 Dec 2020 18:42:10

US3522200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:54:47
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Endocrine neoplasms malignant and unspecified, HLT: Thyroid neoplasms malignant, PT: Papillary thyroid cancer, LLT: Papillary thyroid cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Dec 2020 19:51:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Dec 2020 19:51:04
Data point term sent to Coder	System	04 Dec 2020 19:49:43
User entered 'Papillary Thyroid Cancer'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:54:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:54:52
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:54:53
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

US3522200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 14:15:16
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.' answered with 'Diagnosis was found at checkup. No symptoms were seen.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 14:26:59
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 18:19:15
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:54:55
User entered '1 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 19:49:23



**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:54:57
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:54:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:55:52
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:00
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:04
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:49:23

US3522200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:55:58
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 16:53:10
User entered empty.	System	04 Dec 2020 19:49:23

US3522200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:11

Severity

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
User closed query 'PV Query: Since the subject was hospitalized for the event of thyroidectomy, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:57:18
User closed query 'PV Query: Since event of papillary thyroid cancer was considered Life threatening requiring hospitalization, please consider upgrading severity from grade 2. If not, please clarify seriousness criteria.' (Site from Safety).	(b) (4), (b) (6)	02 Feb 2021 17:57:04
Query 'PV Query: Since the subject was hospitalized for the event of thyroidectomy, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' answered with 'updated' (Site from Safety).	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 13:46:04
Query 'PV Query: Since event of papillary thyroid cancer was considered Life threatening requiring hospitalization, please consider upgrading severity from grade 2. If not, please clarify seriousness criteria.' answered with 'updated' (Site from Safety).	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 13:45:56
DataPoint Un-verified.	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 13:45:43
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Alayna Wilder (b) (4) (b) (4)	02 Feb 2021 13:45:43
User opened query 'PV Query: Since the subject was hospitalized for the event of thyroidectomy, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 1/grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 22:32:25
User opened query 'PV Query: Since event of papillary thyroid cancer was considered Life threatening requiring hospitalization, please consider upgrading severity from grade 2. If not, please clarify seriousness criteria.' (Site from Safety).	(b) (4), (b) (6)	01 Feb 2021 22:28:11
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:55:06

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	04 Dec 2020 20:21:17
reason for change: Data Entry Error		
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	04 Dec 2020 19:49:23



**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:09
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:13
User entered 'I'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:14
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:16
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:17
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:19
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:20
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:49:23



**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:55:22
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 18:55:24
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:26
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:30
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:31
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:33
User entered 'Not Applicable (NOT APPLICABLE)'	Yaman Ahmed (b) (4)	17 Dec 2020 18:21:42
reason for change: Data Entry Error	(b) (4)	
User entered 'None (NONE)'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:38
User entered '0' reason for change: Data Entry Error	Sharon Mathys (b) (4)	18 Dec 2020 19:22:14
User entered '1'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:49:23

US3522200

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:55:39
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4)	18 Dec 2020 19:22:14
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:49:23



US3522200

Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
User closed query 'Please kindly follow-up on 15Jan2021 to see if scheduled surgery was completed. Once done please check and also update Concomitant Procedure page.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 05:53:27
User entered '1' reason for change: Data Entry Error	Sharon Mathys (b) (4)	01 Feb 2021 15:34:08
Query 'Please kindly follow-up on 15Jan2021 to see if scheduled surgery was completed. Once done please check and also update Concomitant Procedure page.' answered with 'updated' (Site from CRA).	Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:28:54
User opened query 'Please kindly follow-up on 15Jan2021 to see if scheduled surgery was completed. Once done please check and also update Concomitant Procedure page.' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 18:57:31
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Un-verified.	(b) (4)	
	Alayna Wilder (b) (4)	22 Jan 2021 20:36:08
	(b) (4)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change:	Alayna Wilder (b) (4)	22 Jan 2021 20:36:08
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:57:36
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 13:30:30
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Unable to reach participant by phone, VM box full, sent email, awaiting reply. Will update when able.' (Site from Safety).	Alayna Wilder (b) (4)	18 Dec 2020 23:22:45
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 16:52:12
	(b) (4), (b) (6)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	04 Dec 2020 19:49:23
	(b) (4), (b) (6)	

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:57:38
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:49:23

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:07:46
User closed query 'Per DM CLR: Narrative = CENTRAL COMPARTMENT LYMPH NODE DISSECTION, LEFT MODIFIED RADICAL NECK DISSECTION. However, these were not recorded in the ConProc eCRF. Please review and ensure that these were captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 04:55:54
Query 'Per DM CLR: Narrative = CENTRAL COMPARTMENT LYMPH NODE DISSECTION, LEFT MODIFIED RADICAL NECK DISSECTION. However, these were not recorded in the ConProc eCRF. Please review and ensure that these were captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	19 Feb 2021 01:32:34
User opened query 'Per DM CLR: Narrative = CENTRAL COMPARTMENT LYMPH NODE DISSECTION, LEFT MODIFIED RADICAL NECK DISSECTION. However, these were not recorded in the ConProc eCRF. Please review and ensure that these were captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 00:07:46

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:56:11

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT JUST DIAGNOSED. SHE WILL BE MEETING WITH A SURGEON IN THE FUTURE AND STARTING SOME MEDICATIONS.  17 DEC 2020 UPDATE: PAPILLARY THYROID CANCER IS STAGE 1 (WILL KEEP GRADE AS GRADE 2) AND SHE WILL BE SEEING A SPECIALIST AT THE END OF DECEMBER 2020 IN PREPARATION FOR SURGERY. ON 05 DEC 2020, TOPIRAMATE WAS STOPPED BECAUSE IT WAS INTERFERING WITH HER BIRTH CONTROL SO SHE WAS SWITCHED TO PROPRANOLOL 40 MG TWICE DAILY ON 05 DEC 2020.  HAD A TOTAL THYROIDECTOMY WITH RLN MONITORING, CENTRAL COMPARTMENT LYMPH NODE DISSECTION, LEFT MODIFIED RADICAL NECK DISSECTION LOGGED AS CONCOM. PROCEDURE  16 Feb 2021: post total thyroidectomy, she underwent radioactive iodine treatment on 11 Feb 2021 for tall cell variant papillary thyroid cancer; Liothyronine was increased from 50 25 microgram to 100 micrograms on 13 Feb 2021.' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	16 Feb 2021 21:16:51

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT JUST DIAGNOSED. SHE WILL BE MEETING WITH A SURGEON IN THE FUTURE AND STARTING SOME MEDICATIONS.  17 DEC 2020 UPDATE: PAPILLARY THYROID CANCER IS STAGE 1 (WILL KEEP GRADE AS GRADE 2) AND SHE WILL BE SEEING A SPECIALIST AT THE END OF DECEMBER 2020 IN PREPARATION FOR SURGERY. ON 05 DEC 2020, TOPIRAMATE WAS STOPPED BECAUSE IT WAS INTERFERING WITH HER BIRTH CONTROL SO SHE WAS SWITCHED TO PROPRANOLOL 40 MG TWICE DAILY ON 05 DEC 2020.  Had a TOTAL THYROIDECTOMY WITH RLN MONITORING, CENTRAL COMPARTMENT LYMPH NODE DISSECTION, LEFT MODIFIED RADICAL NECK DISSECTION logged as concom. procedure' reason for change: New Information DataPoint Un-verified.	Sharon Mathys (b) (4) (b) (4)	01 Feb 2021 15:34:53
User entered 'PATIENT JUST DIAGNOSED. SHE WILL BE MEETING WITH A SURGEON IN THE FUTURE AND STARTING SOME MEDICATIONS.	Sharon Mathys (b) (4) (b) (4)	01 Feb 2021 15:34:08
17 DEC 2020 UPDATE: PAPILLARY THYROID CANCER IS STAGE 1 (WILL KEEP GRADE AS GRADE 2) AND SHE WILL BE SEEING A SPECIALIST AT THE END OF DECEMBER 2020 IN PREPARATION FOR SURGERY. ON 05 DEC 2020, TOPIRAMATE WAS STOPPED BECAUSE IT WAS INTERFERING WITH HER BIRTH CONTROL SO SHE WAS SWITCHED TO PROPRANOLOL 40 MG TWICE DAILY ON 05 DEC 2020.' reason for change: New Information		
User closed query 'PV Query: Please provide the surgical note.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	25 Jan 2021 18:15:22

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide information regarding the clinical context of the event, including how the mass was found, results of imaging diagnosis, and pathological description of the specimen (if applicable).' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 18:15:18
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Jan 2021 18:15:03

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'Laboratory Data: Outside labs 10/21/2020 TSH 1.71  Thyroid Ultrasound (11/24/2020):  Pre-procedural images of the thyroid gland redemonstrate a multinodular thyroid with a left mid nodule measuring 1.7 x 1.1 x 1.1 cm that is hypoechoic, solid, with well-defined margins, fine punctate microcalcifications, and low peripheral vascularity. There is a left level 4 lymph node measuring 2.3 x 2.3 x 1.3 cm that is hypoechoic without a lipid-rich stripe, solid, with well-defined margins, no microcalcifications, and no vascularity.   Ultrasound-guided Thyroid FNA Biopsy (11/24/2020): Ultrasound guided fine needle aspiration biopsy was performed on the left mid thyroid nodule measuring 1.7 cm with a satisfactory specimen acquired and reviewed by Beaumont Cytopathology. Cytopathology reveals three of four aspirate smears are moderately cellular and are adequate for diagnosis. One remaining smear is acellular. There are clusters and fragments of neoplastic follicular cells with enlargement nuclei, hypochromasia, nuclear grooves and rare nuclear pseudoinclusions. The findings are consistent with papillary thyroid carcinoma.  Ultrasound-guided Left level 4 lymph node FNA Biopsy (11/24/2020): Ultrasound guided fine needle aspiration biopsy was performed on the left level 4 lymph node measuring 2.3 cm with a satisfactory specimen acquired and reviewed by Beaumont Cytopathology. Cytopathology reveals three of three aspirate smears are moderately cellular and consist of sheets and clusters of follicular cells with nuclear enlargement, nuclear grooves and pseudoinclusions, consistent with papillary thyroid carcinoma. There is no significant population of lymphocytes. The lack of lymphocytes in this aspirate could represent a completely replaced lymph	Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:35:44



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[Narrative](#)

Audit	User	Time (GMT)
node by metastatic papillary thyroid carcinoma. ' (Site from Safety).		
Query 'PV Query: Please provide the surgical note.' answered with 'Total thyroidectomy with RLN monitoring, Central Compartment Lymph Node Dissection, Left Modified Radical Neck Dissection' (Site from Safety).	Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:31:28
Query 'PV Query: Please provide information regarding the clinical context of the event, including how the mass was found, results of imaging diagnosis, and pathological description of the specimen (if applicable).' answered with 'Subject was able to palpate nodule, brought to PCP's attention, imaging and biopsy done to dx.' (Site from Safety).	Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:30:44
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:57:40
User closed query 'PV Query: Paxil was administered for depression on Oct 19. Is depression a concurrent condition or adverse event?' (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 17:27:08
Query 'PV Query: Paxil was administered for depression on Oct 19. Is depression a concurrent condition or adverse event?' answered with 'was used to treat adjustment disorder with anxiety' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 13:16:15
User opened query 'PV Query: Paxil was administered for depression on Oct 19. Is depression a concurrent condition or adverse event?' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 17:13:16
User opened query 'PV Query: Please provide the surgical note.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 17:12:45
User opened query 'PV Query: Please provide information regarding the clinical context of the event, including how the mass was found, results of imaging diagnosis, and pathological description of the specimen (if applicable).' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 17:12:25
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 17:11:56

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'PATIENT JUST DIAGNOSED. SHE WILL BE MEETING WITH A SURGEON IN THE FUTURE AND STARTING SOME MEDICATIONS.  17 DEC 2020 UPDATE: PAPILLARY THYROID CANCER IS STAGE 1 (WILL KEEP GRADE AS GRADE 2) AND SHE WILL BE SEEING A SPECIALIST AT THE END OF DECEMBER 2020 IN PREPARATION FOR SURGERY. ON 05 DEC 2020, TOPIRAMATE WAS STOPPED BECAUSE IT WAS INTERFERING WITH HER BIRTH CONTROL SO SHE WAS SWITCHED TO PROPRANOLOL 40 MG TWICE DAILY ON 05 DEC 2020. Spoke with subject on 12/18, she has appt to see surgeon on 12/29. Will update at that time.'	Alayna Wilder (b) (4) (b) (4)	18 Dec 2020 23:53:35
reason for change: New Information User closed query 'PV Query: As the event is classified as serious, please consider updating the event severity. If the event is to remain severity grade of 2, please explain.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 20:17:14
User closed query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 20:17:11
User closed query 'PV Query: As the last dose of study drug was given on 18 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 20:17:08
User closed query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 20:17:05

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: As the event is classified as serious, please consider updating the event severity. If the event is to remain severity grade of 2, please explain.' answered with 'it's serious for now, but due to Stage 1 will be grade 2 until she undergoes surgery and then will not be serious post surgery' (Site from Safety).	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:46:43
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so. ' answered with 'new diagnosis ' (Site from Safety).	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:44:37
Query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so. ' answered with 'updated' (Site from Safety).	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:44:21
User entered 'PATIENT JUST DIAGNOSED. SHE WILL BE MEETING WITH A SURGEON IN THE FUTURE AND STARTING SOME MEDICATIONS.	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:44:12
17 Dec 2020 Update: Papillary Thyroid cancer is stage 1 (will keep grade as Grade 2) and she will be seeing a specialist at the end of December 2020 in preparation for surgery. On 05 Dec 2020, Topiramate was stopped because it was interfering with her birth control so she was switched to Propranolol 40 mg twice daily on 05 Dec 2020' reason for change: New Information		
Query 'PV Query: As the last dose of study drug was given on 18 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:21:56
User opened query 'PV Query: As the event is classified as serious, please consider updating the event severity. If the event is to remain severity grade of 2, please explain.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	10 Dec 2020 17:13:42

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so. ' canceled (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 17:11:26
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 17:11:14
User opened query 'PV Query: Please add subject's medical history (prior to onset of study) to medical history eCRF. If none, please state so. ' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 17:09:26
User opened query 'PV Query: As the last dose of study drug was given on 18 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 17:05:01
User opened query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 16:51:41
User entered 'Patient just diagnosed. She will be meeting with a surgeon in the future and starting some medications.'	(b) (4), (b) (6)	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Dec 2020 19:49:23

**US3522200**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Dec 2020 19:49:23

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:56:11

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Per ETRTR: Medications were dosed for SAE "Papillary Thyroid Cancer". Please ensure that "Other Action Taken" within SAE CRF page indicates that Concomitant Medication was dosed (mark checkbox for Concomitant Medications), thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 05:53:39
User closed query 'Per DM CLR: Per Diary Dose 1 Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 05:19:16
Query 'Per DM CLR: Per Diary Dose 1 Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Aleve was previously recorded in con meds.' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	08 Feb 2021 18:30:37
User opened query 'Per DM CLR: Per Diary Dose 1 Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 08:08:00
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:57:50

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:56:11

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per ETRTR: Medications were dosed for SAE Sharon Mathys (b) (4) "Papillary Thyroid Cancer". Please ensure that "Other (b) (4) Action Taken" within SAE CRF page indicates that Concomitant Medication was dosed (mark checkbox for Concomitant Medications), thanks.' answered with 'Has been checked' (Site from CRA).		18 Dec 2020 19:26:00
User opened query 'Per ETRTR: Medications were dosed for SAE "Papillary Thyroid Cancer". Please ensure that "Other Action Taken" within SAE CRF page indicates that Concomitant Medication was dosed (mark checkbox for Concomitant Medications), thanks.' (Site from CRA).	(b) (4), (b) (6)	18 Dec 2020 18:53:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Aug 2020 12:23:30



US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORETHISTERONE ACETATE, PRODUCTSYNONYM: MICROGESTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 14:29:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 14:29:04
Data point term sent to Coder	System	20 Jan 2021 14:24:49
Coding entries removed.	Sharon Mathys (b) (4)	20 Jan 2021 14:23:58
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;FERROUS FUMARATE;NORETHISTERONE ACETATE, PRODUCTSYNONYM: MICROGESTIN FE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 08:48:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 08:48:10
Data point term sent to Coder	System	08 Oct 2020 14:45:16
Coding entries removed.	Alayna Wilder (b) (4)	08 Oct 2020 14:44:23
User entered 'MICROGESTIN FE Norgestimate/ethinyl estradiol' reason for change: New Information	Alayna Wilder (b) (4)	08 Oct 2020 14:44:23

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:11

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORETHISTERONE ACETATE, PRODUCTSYNONYM: MICROGESTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 07:23:33
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 Sep 2020 07:23:33
Data point term sent to Coder	System	02 Sep 2020 15:29:27
Coding entries removed.	Sharon Mathys (b) (4) (b) (4)	02 Sep 2020 15:28:31
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ETHINYLESTRADIOL;NORETHISTERONE ACETATE, PRODUCTSYNONYM: MICROGESTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:07:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:07:05
Data point term sent to Coder	System	19 Aug 2020 13:02:57
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 13:02:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 13:02:02
User entered 'microgestin' reason for change: New Information	(b) (4), (b) (6) (b) (4)	19 Aug 2020 13:02:02
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 12:36:06
User entered empty.	(b) (4), (b) (6) (b) (4)	19 Aug 2020 12:36:06

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EAB) (1725)

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US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Alayna Wilder (b) (4)	08 Oct 2020 14:44:23
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Aug 2020 12:36:06

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered 'BIRTH CONTROL' reason for change: Data Entry Error	Sharon Mathys (b) (4)	20 Jan 2021 14:23:58
	(b) (4)	
User entered 'BIRTHCONTROL' reason for change: Data Entry Error	Sharon Mathys (b) (4)	02 Sep 2020 15:28:31
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 13:02:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 13:02:02
User entered 'birthcontrol' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Aug 2020 13:02:02
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 12:36:06
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:36:06

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
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 using slash (e.g. 5/325).' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Oct 2020 09:03:24
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 using slash (e.g. 5/325).' answered with '1.5/30' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	08 Oct 2020 14:45:48
User entered '1.5/30' reason for change: Data Entry Error	Alayna Wilder (b) (4) (b) (4)	08 Oct 2020 14:44:23
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 using slash (e.g. 5/325).' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:36:27
User entered '1.5'	(b) (4), (b) (6)	19 Aug 2020 12:36:06

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Alayna Wilder (b) (4)	08 Oct 2020 14:44:23
Data Entry Error	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Aug 2020 12:36:06

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered 'mg/mcg' reason for change: Data Entry Error	Alayna Wilder (b) (4)	08 Oct 2020 14:44:23
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:36:06

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:36:06



US3522200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:36:06

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:36:06

US3522200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:36:06

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	19 Aug 2020 14:26:36
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 12:36:06
User entered 'UN Apr 2019'	(b) (4), (b) (6)	19 Aug 2020 12:36:06

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:36:06

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:36:06

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Aug 2020 12:36:06

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:56:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 13:02:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 13:02:02
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	19 Aug 2020 13:02:02
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 12:36:06
User entered empty.	(b) (4), (b) (6)	19 Aug 2020 12:36:06



**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 12:36:06

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 12:36:06

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 12:36:06

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
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 SODIUM, PRODUCTSYNONYM: ALEVE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 15:45:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 15:45:46
Data point term sent to Coder	System	26 Aug 2020 14:10:29
User entered 'Aleve'	Yaman Ahmed (b) (4)	26 Aug 2020 14:09:45
	(b) (4)	

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:09:45

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:11

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION/BLOOD DRAW SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION/BLOOD DRAW SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 10:22:26
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION/BLOOD DRAW SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION/BLOOD DRAW SITE did not meet the AE reporting criteria.' answered with 'Pt took Aleve for pain control on day 2 after 1st injection, solicited event, no adverse reporting needed? Pt did not meet any of the SAE criteria.' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	08 Oct 2020 14:49:55

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:11

Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT INJECTION/BLOOD DRAW SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT INJECTION/BLOOD DRAW SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 06:37:15
User entered 'pain at injection/blood draw site'	Yaman Ahmed (b) (4) (b) (4)	26 Aug 2020 14:09:45

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '440'	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:09:45



US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'mg (mg)'	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:09:45

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:09:45

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'once (ONCE)'	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:09:45

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:09:45

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'Oral (ORAL)'	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:09:45

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:09:45

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '19 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:09:45

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '0'	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:09:45



**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'No (N)'	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:09:45

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '19 Aug 2020'	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:09:45

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:56:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	26 Aug 2020 14:09:45

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User entered empty.	System	26 Aug 2020 14:09:45

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User entered empty.	System	26 Aug 2020 14:09:45

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:50
User entered empty.	System	26 Aug 2020 14:09:45

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 20:16:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 20:16:48
Data point term sent to Coder	System	02 Oct 2020 17:50:03
User entered 'flu vaccine'	(b) (4), (b) (6)	02 Oct 2020 17:49:32

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:49:32



US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	02 Oct 2020 17:49:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 17:49:46
User entered '14 days post 2nd IP' reason for change: New Information	(b) (4), (b) (6)	02 Oct 2020 17:49:46
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 17:49:32
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 17:49:32

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:11**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:49:32

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:11**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:49:32

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'shot'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:49:32

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:49:32

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:49:32

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:49:32

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:49:32



US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:11

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:49:32

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:49:32

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:11**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:49:32

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '2 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:49:32

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:56:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:49:32

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User entered empty.	System	02 Oct 2020 17:49:32

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User entered empty.	System	02 Oct 2020 17:49:32

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:37:53
User entered empty.	System	02 Oct 2020 17:49:32



US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: PAROXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PAXIL [PAROXETINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Dec 2020 14:36:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:36:17
Data point term sent to Coder	System	28 Dec 2020 13:16:46
Coding entries removed.	(b) (4), (b) (6)	28 Dec 2020 13:15:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: PAROXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PAXIL [PAROXETINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 13:46:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 13:46:55
Data point term sent to Coder	System	23 Oct 2020 13:24:40
User entered 'Paxil'	(b) (4), (b) (6)	23 Oct 2020 13:24:29

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 13:24:29

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:11

Indication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ADJUSTMENT DISORDER WITH ANXIETY worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 09:51:58
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ADJUSTMENT DISORDER WITH ANXIETY worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'Not worsened, pcp seeking better management for improvement' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	08 Feb 2021 18:26:11
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of ADJUSTMENT DISORDER WITH ANXIETY worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 03:15:52
User entered 'adjustment disorder with anxiety' reason for change: Per Query Resolution	(b) (4), (b) (6)	28 Dec 2020 13:15:48
User entered 'Depression'	(b) (4), (b) (6)	23 Oct 2020 13:24:29

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '10'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:24:29

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:24:29

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:24:29

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:24:29

US3522200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:24:29



**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:24:29

US3522200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:24:29

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:24:29

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:24:29

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:24:29

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:24:29

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:56:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Oct 2020 13:24:29

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 13:24:29



**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 13:24:29

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 13:24:29

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 07:31:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 07:31:57
Data point term sent to Coder	System	22 Jan 2021 20:39:34
Coding entries removed.	Alayna Wilder (b) (4)	22 Jan 2021 20:38:36
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 12:08:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 12:08:50
Data point term sent to Coder	System	04 Dec 2020 19:52:44
User entered 'topiramate'	(b) (4), (b) (6)	04 Dec 2020 19:52:03

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:16
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 19:52:03

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
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)	25 Jan 2021 05:31:50
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 'unknown' (Site from DM).	Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:38:48
DataPoint Un-verified.	Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:38:36
User entered 'not clearly known by participant' reason for change: Data Entry Error	Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:38:36
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)	21 Jan 2021 21:01:31
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:16
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 19:52:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 19:52:28
User entered 'Papillary Thyroid Cancer' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Dec 2020 19:52:28
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 19:52:03
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:52:03

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:11**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:16
User entered '25'	(b) (4), (b) (6)	04 Dec 2020 19:52:03

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:11**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:16
User entered 'mg (mg)'	(b) (4), (b) (6)	04 Dec 2020 19:52:03

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:11**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:16
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:52:03



**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:11**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:16
User entered 'twice daily (BID)'	(b) (4), (b) (6)	04 Dec 2020 19:52:03

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:16
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:52:03

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:11**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:16
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	04 Dec 2020 19:52:03

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:11**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:16
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:52:03

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:16
User entered '04 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 19:52:03

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:16
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 19:52:03

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:56:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:16
User entered 'No (N)' reason for change: New Information	Yaman Ahmed (b) (4)	17 Dec 2020 18:47:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 19:52:03

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:16
User entered '5 Dec 2020' reason for change: New Information	Yaman Ahmed (b) (4)	17 Dec 2020 18:47:38
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:52:03



**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:16
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 19:52:03

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User entered '2'	System	04 Dec 2020 19:52:03

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User entered '1'	System	04 Dec 2020 19:52:03

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:00
User entered '804 (804)'	System	04 Dec 2020 19:52:03

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: ANTITHYROID PREPARATIONS, ATC: OTHER ANTITHYROID PREPARATIONS, PRODUCT: PROPRANOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:33:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 21:33:48
Data point term sent to Coder	System	17 Dec 2020 18:49:33
User entered 'Propranolol'	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:48:36

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:48:36

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:56:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User entered 'PAPILLARY THYROID CANCER'	Yaman Ahmed (b) (4)	17 Dec 2020 18:48:52
reason for change: Data Entry Error	(b) (4)	
User entered 'Papillary Thyroid CA'	Yaman Ahmed (b) (4)	17 Dec 2020 18:48:36
	(b) (4)	

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User entered '40'	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:48:36



**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User entered 'mg (mg)'	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:48:36

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:48:36

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User entered 'twice daily (BID)'	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:48:36

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:48:36

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:48:36

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:48:36

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User entered '5 Dec 2020'	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:48:36

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:48:36



**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:48:36

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:48:36

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:21
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	17 Dec 2020 18:48:36

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	17 Dec 2020 18:48:36

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 18:48:36

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Dec 2020 18:48:36

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOTHYRONINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 13:37:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 13:37:45
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Mar 2021 15:18:43
Data point term sent to Coder	System	09 Mar 2021 19:25:06
Coding entries removed.	(b) (4), (b) (6)	09 Mar 2021 19:24:17
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOTHYRONINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 20:49:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Jan 2021 20:49:52
Data point term sent to Coder	System	22 Jan 2021 20:13:01
User entered 'liothyronine'	Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:12:44

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'No (N)'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:12:44



US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this Con Med is being used to treat/prevent. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 03:54:17
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this Con Med is being used to treat/prevent. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 19:24:25
User entered 'Hypo-Thyroid' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Mar 2021 19:24:17
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this Con Med is being used to treat/prevent. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 08:36:19
User entered 'post-thyroidectomy'	Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:12:44

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:11**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '25'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:12:44

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'ug (ug)'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:12:44

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:12:44

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'once daily (QD)'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:12:44
	(b) (4)	

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:12:44

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'Oral (ORAL)'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:12:44

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered empty.	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:12:44



US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 03:55:24
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate.	(b) (4), (b) (6)	09 Mar 2021 19:25:09
' answered with 'correct; after her procedure she was placed on this medication ' (Site from DM).		
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding Con Proc Please review and reconcile Con Med and Con Proc start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 01:26:21
User entered '18 Jan 2021'	Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:12:44

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '0'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:12:44

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'No (N)' reason for change: New Information	(b) (4) Yaman Ahmed (b) (4)	16 Feb 2021 21:12:21
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:12:44

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered '13 Feb 2021' reason for change: New Information	(b) (4)	
	Yaman Ahmed (b) (4)	16 Feb 2021 21:12:21
User entered empty.	(b) (4)	
	Alayna Wilder (b) (4)	22 Jan 2021 20:12:44
	(b) (4)	

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:56:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User entered 'No (N)'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:12:44

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User entered '1'	System	22 Jan 2021 20:12:44

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User entered '1'	System	22 Jan 2021 20:12:44

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:38:07
User entered '804 (804)'	System	22 Jan 2021 20:12:44



US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LIOTHYRONINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Mar 2021 07:17:01
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 Mar 2021 07:17:01
Data point term sent to Coder	System	16 Feb 2021 21:13:41
User entered 'Liothyronine'	Yaman Ahmed (b) (4) (b) (4)	16 Feb 2021 21:13:33

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:11**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered 'No (N)'	Yaman Ahmed (b) (4)	16 Feb 2021 21:13:33
	(b) (4)	

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 03:54:24
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' answered with 'Medical history updated' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 19:27:38
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 01:26:55
User entered 'hypothyroidism post thyroidectomy'	Yaman Ahmed (b) (4) (b) (4)	16 Feb 2021 21:13:33

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:11**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered '100'	Yaman Ahmed (b) (4)	16 Feb 2021 21:13:33
	(b) (4)	

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered 'ug (ug)'	Yaman Ahmed (b) (4)	16 Feb 2021 21:13:33
	(b) (4)	

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	16 Feb 2021 21:13:33
	(b) (4)	

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered 'once daily (QD)'	Yaman Ahmed (b) (4)	16 Feb 2021 21:13:33
	(b) (4)	

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	16 Feb 2021 21:13:33
	(b) (4)	



**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:11**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered 'Oral (ORAL)'	Yaman Ahmed (b) (4)	16 Feb 2021 21:13:33
	(b) (4)	

US3522200

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:11**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	16 Feb 2021 21:13:33
	(b) (4)	

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered '13 Feb 2021'	Yaman Ahmed (b) (4)	16 Feb 2021 21:13:33
	(b) (4)	

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:11**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered '0'	Yaman Ahmed (b) (4)	16 Feb 2021 21:13:33
	(b) (4)	

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:11**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	16 Feb 2021 21:13:33
	(b) (4)	

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered empty.	Yaman Ahmed (b) (4)	16 Feb 2021 21:13:33
	(b) (4)	

US3522200

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:56:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:18:43
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	16 Feb 2021 21:13:39
	(b) (4)	
User entered 'Yes (Y)'	Yaman Ahmed (b) (4)	16 Feb 2021 21:13:33
	(b) (4)	

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:11**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 21:13:33



**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 21:13:33

**US3522200**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:56:11**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Feb 2021 21:13:33

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 07:56:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:18
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	22 Jan 2021 20:39:01
User entered 'No (N)'	Alayna Wilder (b) (4)	19 Aug 2020 12:23:15
	(b) (4)	
	(b) (4), (b) (6)	

US3522200

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 07:56:11**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
	(b) (4)	
User entered '24 Nov 2020'	Alayna Wilder (b) (4)	22 Jan 2021 20:39:35
	(b) (4)	

**US3522200**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
	(b) (4)	
User entered 'thyroid ultrasound'	Alayna Wilder (b) (4)	22 Jan 2021 20:39:35
	(b) (4)	

**US3522200**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:39:35

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:56:11

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
	(b) (4)	
User entered empty.	Alayna Wilder (b) (4)	22 Jan 2021 20:39:35
	(b) (4)	

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:56:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '24 Nov 2020'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:40:08
	(b) (4)	



US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:56:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'thyroid FNA biopsy'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:40:08

**US3522200**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:40:08

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:56:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:40
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:40:08

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 07:56:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:45
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '15 Jan 2021'	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:41:08

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 07:56:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:45
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'thyroidectomy'	(b) (4) Alayna Wilder (b) (4) (b) (4)	22 Jan 2021 20:41:08

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 07:56:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:45
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Adverse Event (AE)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	01 Feb 2021 15:32:25
User entered 'Medical History (MH)'	Alayna Wilder (b) (4)	22 Jan 2021 20:41:08

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 07:56:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:45
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) Alayna Wilder (b) (4)	22 Jan 2021 20:41:08

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 07:56:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '11 Feb 2021'	Yaman Ahmed (b) (4)	16 Feb 2021 21:19:42



US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 07:56:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'radioactive iodine treatment'	Yaman Ahmed (b) (4)	16 Feb 2021 21:19:42

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 07:56:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Adverse Event (AE)'	Yaman Ahmed (b) (4)	16 Feb 2021 21:19:42

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 10 Jun 2021 07:56:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:54
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	Yaman Ahmed (b) (4)	16 Feb 2021 21:19:42

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 07:56:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 01:34:43
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 01:34:43
User entered '16 Feb 2021' reason for change: Data Entry Error	Alayna Wilder (b) (4)	19 Feb 2021 01:34:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 01:33:13
User entered empty.	System	19 Feb 2021 01:33:13
	Alayna Wilder (b) (4)	19 Feb 2021 01:33:13
	(b) (4)	

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 07:56:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'CENTRAL COMPARTMENT LYMPH NODE DISSECTION'	(b) (4) Alayna Wilder (b) (4) (b) (4)	19 Feb 2021 01:33:13

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 07:56:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Adverse Event (AE)'	(b) (4) Alayna Wilder (b) (4)	19 Feb 2021 01:33:13

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 07:56:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:01
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) Alayna Wilder (b) (4)	19 Feb 2021 01:33:13

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 07:56:11

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 01:34:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 01:34:52
User entered '16 Feb 2021' reason for change: Data Entry Error	Alayna Wilder (b) (4)	19 Feb 2021 01:34:52
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Feb 2021 01:33:33
User entered empty.	System	19 Feb 2021 01:33:33
	Alayna Wilder (b) (4)	19 Feb 2021 01:33:33
	(b) (4)	



US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 07:56:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'LEFT MODIFIED RADICAL NECK DISSECTION.'	(b) (4) Alayna Wilder (b) (4)	19 Feb 2021 01:33:33

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 07:56:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'Adverse Event (AE)'	(b) (4) Alayna Wilder (b) (4)	19 Feb 2021 01:33:33

US3522200

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 07:56:11

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:59:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered empty.	(b) (4) Alayna Wilder (b) (4)	19 Feb 2021 01:33:33

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'USA-US131-2020-MRNA-1273-P301000012'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 17:19:22
Un-reviewed for Safety.	System	02 Feb 2021 17:57:55
User entered 'No (N)'	System	02 Feb 2021 17:57:55
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:17:22
Un-reviewed for Safety.	System	25 Jan 2021 18:17:09
DataPoint Un-verified.	System	25 Jan 2021 18:17:09
User entered 'Yes (Y)'	System	25 Jan 2021 18:17:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Paul'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Kilgore'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6)	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'MI'	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:13:52
User entered 'US'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	17 Feb 2021 17:19:41
User entered '6'	System	02 Feb 2021 17:57:55
User entered '5'	System	25 Jan 2021 18:17:34
User entered '4'	System	29 Dec 2020 17:43:12
User entered '3'	System	21 Dec 2020 13:30:47
User entered '2'	System	17 Dec 2020 20:14:52
User entered '1'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'USA-US131-2020-MRNA-1273-P301000012'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 17:19:22
Un-reviewed for Safety.	System	02 Feb 2021 17:57:55
User entered 'No (N)'	System	02 Feb 2021 17:57:55
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:17:22
Un-reviewed for Safety.	System	25 Jan 2021 18:17:09
DataPoint Un-verified.	System	25 Jan 2021 18:17:09
User entered 'Yes (Y)'	System	25 Jan 2021 18:17:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Paul'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Kilgore'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'MI'	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:13:52
User entered 'US'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	17 Feb 2021 17:19:41
User entered '6'	System	02 Feb 2021 17:57:55
User entered '5'	System	25 Jan 2021 18:17:34
User entered '4'	System	29 Dec 2020 17:43:12
User entered '3'	System	21 Dec 2020 13:30:47
User entered '2'	System	17 Dec 2020 20:14:52
User entered '1'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 07:56:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
User entered '05/Dec/2020 18:42'	System	05 Dec 2020 18:42:32

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:56:11

**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.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:13:52
User entered 'I'	(b) (4), (b) (6)	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'USA-US131-2020-MRNA-1273-P301000012'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 17:19:22
Un-reviewed for Safety.	System	02 Feb 2021 17:57:55
User entered 'No (N)'	System	02 Feb 2021 17:57:55
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:17:22
Un-reviewed for Safety.	System	25 Jan 2021 18:17:09
DataPoint Un-verified.	System	25 Jan 2021 18:17:09
User entered 'Yes (Y)'	System	25 Jan 2021 18:17:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Paul'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Kilgore'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'MI'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:13:52
User entered 'US'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	17 Feb 2021 17:19:41
User entered '6'	System	02 Feb 2021 17:57:55
User entered '5'	System	25 Jan 2021 18:17:34
User entered '4'	System	29 Dec 2020 17:43:12
User entered '3'	System	21 Dec 2020 13:30:47
User entered '2'	System	17 Dec 2020 20:14:52
User entered '1'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 07:56:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
User entered '17/Dec/2020 15:14'	System	17 Dec 2020 20:14:52

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:56:11

**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.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:14:57
User entered 'I'	(b) (4), (b) (6)	17 Dec 2020 20:14:52

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'USA-US131-2020-MRNA-1273-P301000012'	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 17:19:22
Un-reviewed for Safety.	System	02 Feb 2021 17:57:55
User entered 'No (N)'	System	02 Feb 2021 17:57:55
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:17:22
Un-reviewed for Safety.	System	25 Jan 2021 18:17:09
DataPoint Un-verified.	System	25 Jan 2021 18:17:09
User entered 'Yes (Y)'	System	25 Jan 2021 18:17:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Paul'	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Kilgore'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'MI'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:13:52
User entered 'US'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	17 Feb 2021 17:19:41
User entered '6'	System	02 Feb 2021 17:57:55
User entered '5'	System	25 Jan 2021 18:17:34
User entered '4'	System	29 Dec 2020 17:43:12
User entered '3'	System	21 Dec 2020 13:30:47
User entered '2'	System	17 Dec 2020 20:14:52
User entered '1'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 07:56:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
User entered '21/Dec/2020 13:30'	System	21 Dec 2020 13:30:47



US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:56:11

**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.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	29 Dec 2020 17:42:57
User entered 'I'	(b) (4), (b) (6)	21 Dec 2020 13:30:47

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'USA-US131-2020-MRNA-1273-P301000012'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 17:19:22
Un-reviewed for Safety.	System	02 Feb 2021 17:57:55
User entered 'No (N)'	System	02 Feb 2021 17:57:55
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:17:22
Un-reviewed for Safety.	System	25 Jan 2021 18:17:09
DataPoint Un-verified.	System	25 Jan 2021 18:17:09
User entered 'Yes (Y)'	System	25 Jan 2021 18:17:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Paul'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Kilgore'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'MI'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:13:52
User entered 'US'	System	05 Dec 2020 18:42:32



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	17 Feb 2021 17:19:41
User entered '6'	System	02 Feb 2021 17:57:55
User entered '5'	System	25 Jan 2021 18:17:34
User entered '4'	System	29 Dec 2020 17:43:12
User entered '3'	System	21 Dec 2020 13:30:47
User entered '2'	System	17 Dec 2020 20:14:52
User entered '1'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 07:56:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
User entered '29/Dec/2020 12:43'	System	29 Dec 2020 17:43:12

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:56:11

**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.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 18:17:22
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:35
User entered 'I'	(b) (4), (b) (6)	29 Dec 2020 17:43:12

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'USA-US131-2020-MRNA-1273-P301000012'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 17:19:22
Un-reviewed for Safety.	System	02 Feb 2021 17:57:55
User entered 'No (N)'	System	02 Feb 2021 17:57:55
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:17:22
Un-reviewed for Safety.	System	25 Jan 2021 18:17:09
DataPoint Un-verified.	System	25 Jan 2021 18:17:09
User entered 'Yes (Y)'	System	25 Jan 2021 18:17:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Paul'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Kilgore'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'MI'	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:13:52
User entered 'US'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	17 Feb 2021 17:19:41
User entered '6'	System	02 Feb 2021 17:57:55
User entered '5'	System	25 Jan 2021 18:17:34
User entered '4'	System	29 Dec 2020 17:43:12
User entered '3'	System	21 Dec 2020 13:30:47
User entered '2'	System	17 Dec 2020 20:14:52
User entered '1'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 07:56:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '25/Jan/2021 13:17'	(b) (4) System	25 Jan 2021 18:17:34

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 07:56:11

**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.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 17:57:39
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 18:17:34

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'USA-US131-2020-MRNA-1273-P301000012'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 17:19:22
Un-reviewed for Safety.	System	02 Feb 2021 17:57:55
User entered 'No (N)'	System	02 Feb 2021 17:57:55
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:17:22
Un-reviewed for Safety.	System	25 Jan 2021 18:17:09
DataPoint Un-verified.	System	25 Jan 2021 18:17:09
User entered 'Yes (Y)'	System	25 Jan 2021 18:17:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Paul'	System	05 Dec 2020 18:42:10

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 07:56:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Kilgore'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'MI'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:13:52
User entered 'US'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	17 Feb 2021 17:19:41
User entered '6'	System	02 Feb 2021 17:57:55
User entered '5'	System	25 Jan 2021 18:17:34
User entered '4'	System	29 Dec 2020 17:43:12
User entered '3'	System	21 Dec 2020 13:30:47
User entered '2'	System	17 Dec 2020 20:14:52
User entered '1'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 07:56:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '02/Feb/2021 12:57'	(b) (4) System	02 Feb 2021 17:57:55

US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 07:56:11

**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.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:19:22
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 17:57:55

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'USA-US131-2020-MRNA-1273-P301000012'	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Yes (Y)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 17:19:22
Un-reviewed for Safety.	System	02 Feb 2021 17:57:55
User entered 'No (N)'	System	02 Feb 2021 17:57:55
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:17:22
Un-reviewed for Safety.	System	25 Jan 2021 18:17:09
DataPoint Un-verified.	System	25 Jan 2021 18:17:09
User entered 'Yes (Y)'	System	25 Jan 2021 18:17:09
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'No (N)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Paul'	System	05 Dec 2020 18:42:10



**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'Kilgore'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6) '	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered 'MI'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 18:42:24
User entered (b) (6)'	System	05 Dec 2020 18:42:10

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:58:35
Reviewed for Safety.	(b) (4), (b) (6)	17 Dec 2020 20:13:52
User entered 'US'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 07:56:11**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	17 Feb 2021 17:19:41
User entered '6'	System	02 Feb 2021 17:57:55
User entered '5'	System	25 Jan 2021 18:17:34
User entered '4'	System	29 Dec 2020 17:43:12
User entered '3'	System	21 Dec 2020 13:30:47
User entered '2'	System	17 Dec 2020 20:14:52
User entered '1'	System	05 Dec 2020 18:42:32

**US3522200**

**Folder: SAE USA-US131-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 07:56:11**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered '17/Feb/2021 11:19'	(b) (4) System	17 Feb 2021 17:19:41



US3522200

Folder: SAE USA-US131-2020-MRNA-1273-P301000012

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 07:56:11

**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.	Marcus Zervos (b) (4)	05 Mar 2021 15:37:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Feb 2021 17:19:41