

US3192575 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:03:43

All time stamps listed in this document are displayed in GMT

US3192575

Form: Participant Creation

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

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Participant ID

US3192575

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

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US3192575

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Date of Birth (MMM yyyy)	(b) (6) 1990
Age	30
Age Units	YEARS
Age (Derived)	30
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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Date of Informed Consent ( <i>dd MMM yyyy</i> )	29 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 14 Feb 2021 03:10:34

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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) 14 Feb 2021 03:10:34

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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) 14 Feb 2021 03:10:34

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



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 03:10:34

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	29 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	10:45 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 10:45
Height ( <i>xxx.x</i> )	67 in
Weight ( <i>xxx.x</i> )	154.6 lb
BMI ( <i>xxx.x</i> )	24.26441 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) 14 Feb 2021 03:10:34

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 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) 14 Feb 2021 03:10:34

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Date of assessment (dd MMM yyyy) 29 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) 14 Feb 2021 03:10:34

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Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	29 AUG 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	29 AUG 2020
Collection time	11:05
Collection date and time (derived)	29 AUG 2020 11:05

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 03:10:34

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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**

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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) 14 Feb 2021 03:10:34

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<b>Resides in Multi-family dwelling</b> (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
<b>Resides in high density housing</b> (e.g., high rise apartments with shared entrances or elevators)	False
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	True
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 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) 14 Feb 2021 03:10:34

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

What was the participant's randomization number? 109983

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

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) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 10:45
Temperature (xxx.x)	96.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 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) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 AUG 2020
Time of assessment (00:00-23:59)	11:58 (24 HR)
Vital Signs Date and Time (derived)	29 AUG 2020 11:58
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:10:34

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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) 14 Feb 2021 03:10:34

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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) 14 Feb 2021 03:10:34

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Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 29 AUG 2020

What was the treatment time? (00:00-23:59) 11:26 (24 HR)

Treatment Date and Time (derived) 29 AUG 2020 11:26

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) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 AUG 2020

Collection time (00:00-23:59)

11:15 (24 HR)

Collection date and time (derived)

29 AUG 2020 11:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Collection date (dd MMM yyyy)			29 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:11	29 AUG 2020 11:11
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 11:54

PC Open Date & Time

29 AUG 2020 11:46

PC Close Date & Time

29 AUG 2020 14:16

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**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 96.8 °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	29 AUG 2020 20:54
PC Open Date & Time	29 AUG 2020 15:11
PC Close Date & Time	30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:03:43

**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

95.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 18:31

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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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

97.2 °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

31 AUG 2020 20:30

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:03:43

**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

95.5 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

01 SEP 2020 18:19

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:03:43

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	03 SEP 2020 05:17
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 20:58

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

04 SEP 2020 21:35

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

**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

29 AUG 2020 11:54

PC Open Date & Time

29 AUG 2020 11:46

PC Close Date & Time

29 AUG 2020 14:16

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**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

29 AUG 2020 20:55

PC Open Date & Time

29 AUG 2020 15:11

PC Close Date & Time

30 AUG 2020 11:59

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 18:30

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 20:31

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 18:18

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:03:43

**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

03 SEP 2020 05:17

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 20:59

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 21:35

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

**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 ☐

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 11:55
PC Open Date & Time	29 AUG 2020 11:46
PC Close Date & Time	29 AUG 2020 14:16

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**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 ☐

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 20:55
PC Open Date & Time	29 AUG 2020 15:11
PC Close Date & Time	30 AUG 2020 11:59

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:03:43

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 18:31
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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 ☒



US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:03:43

**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 ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:03:43

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

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:03:43

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 ☒

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:03:43

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 05:17
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:03:43

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 ☒

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:03:43

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 20:59
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:03:43

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 ☒



US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:03:43

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 21:36
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3192575

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:10:24

Generated On: 11 Aug 2021 22:03:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3192575

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:10:24

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192575

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 04:02:58

Generated On: 11 Aug 2021 22:03:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3192575

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 04:02:58

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192575

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:10:24

Generated On: 11 Aug 2021 22:03:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3192575

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:10:24

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192575

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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



US3192575

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

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)	26 SEP 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 11:25
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3192575

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	26 SEP 2020
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	26 SEP 2020 12:30
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3192575

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 SEP 2020

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

US3192575

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	26 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)	

US3192575

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

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) 26 SEP 2020

What was the treatment time? (00:00-23:59) 11:59 (24 HR)

Treatment Date and Time (derived) 26 SEP 2020 11:59

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

US3192575

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 SEP 2020

Collection time (00:00-23:59)

11:45 (24 HR)

Collection date and time (derived)

26 SEP 2020 11:45

US3192575

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Collection date (dd MMM yyyy)			26 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:51	26 SEP 2020 11:51
Nasopharyngeal Swab 2	No		

US3192575

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 12:22

PC Open Date & Time

26 SEP 2020 12:19

PC Close Date & Time

26 SEP 2020 14:49

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	26 SEP 2020 16:10
PC Open Date & Time	26 SEP 2020 15:44
PC Close Date & Time	27 SEP 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:03:43

**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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 17:48

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:03:43

**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

97.1 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 SEP 2020 05:05

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:03:43

**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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 19:24

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:03:43

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 20:59

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 05:59

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 21:51

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59



US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

**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

26 SEP 2020 12:22

PC Open Date & Time

26 SEP 2020 12:19

PC Close Date & Time

26 SEP 2020 14:49

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**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

26 SEP 2020 16:10

PC Open Date & Time

26 SEP 2020 15:44

PC Close Date & Time

27 SEP 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:03:43

**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

27 SEP 2020 17:49

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 05:05

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:03:43

**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

29 SEP 2020 19:25

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:03:43

**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

30 SEP 2020 21:00

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 05:59

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 21:51

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59



US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

**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 ☐

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 12:22
PC Open Date & Time	26 SEP 2020 12:19
PC Close Date & Time	26 SEP 2020 14:49

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**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 ☐

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

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

No ☒

Yes ☐

PC Time stamp	26 SEP 2020 16:10
PC Open Date & Time	26 SEP 2020 15:44
PC Close Date & Time	27 SEP 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:03:43

**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 ☒

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:03:43

		Yes <input type="checkbox"/>
PC Time stamp	27 SEP 2020 17:49	
PC Open Date & Time	27 SEP 2020 12:00	
PC Close Date & Time	28 SEP 2020 11:59	

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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

94 of 2140

EAB) (1725)

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:03:43

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 05:06
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59



US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:03:43

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 ☒

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:03:43

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 19:25
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:03:43

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

98 of 2140

EAB) (1725)

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:03:43

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 21:00
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:03:43

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 ☒

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:03:43

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 06:00
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:03:43

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 ☒

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:03:43

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 21:52
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59



US3192575

Folder: Diary Dose 2 (1)

Form: Fatigue\_Day(8)

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

03 OCT 2020 16:55

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3192575

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:03:43

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	03 OCT 2020 16:55
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3192575

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:10:24

Generated On: 11 Aug 2021 22:03:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3192575

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:10:24

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192575

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:10:24

Generated On: 11 Aug 2021 22:03:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3192575

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:10:24

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192575

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:10:24

Generated On: 11 Aug 2021 22:03:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3192575

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:10:24

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3192575

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:10:35

Generated On: 11 Aug 2021 22:03:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3192575

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 03:10:35

Generated On: 11 Aug 2021 22:03:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	11:46 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 11:46
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192575

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:10:35

Generated On: 11 Aug 2021 22:03:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3192575

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 03:10:35

Generated On: 11 Aug 2021 22:03:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 OCT 2020
Collection time (00:00-23:59)	12:00 (24 HR)
Collection date and time (derived)	22 OCT 2020 12:00

US3192575

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:10:34

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192575

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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

29 OCT 2020 13:06:17

Patient Cloud Open Date & Time

29 OCT 2020 00:01

Patient Cloud Close Date & Time

02 NOV 2020 23:59

US3192575

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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

06 NOV 2020 11:32:01

Patient Cloud Open Date & Time

05 NOV 2020 00:01

Patient Cloud Close Date & Time

09 NOV 2020 23:59

US3192575

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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

12 NOV 2020 17:12:55

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 NOV 2020 16:40:04
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 20:57:08
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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	01 DEC 2020 17:42:26
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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

09 DEC 2020 13:18:10

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 19:19:39
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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

22 DEC 2020 13:02:03

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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	29 DEC 2020 09:46:36
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	06 JAN 2021 08:44:28
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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

13 JAN 2021 15:54:10

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 07:46:53

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 JAN 2021 10:59:20

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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

01 FEB 2021 09:52:25

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <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 FEB 2021 15:41:06
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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

18 FEB 2021 18:25:49

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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

24 FEB 2021 16:09:14

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	False
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	02 MAR 2021 13:15:32
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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

08 MAR 2021 06:17:56

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <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 MAR 2021 13:23:22
Patient Cloud Open Date & Time	15 MAR 2021 00:01
Patient Cloud Close Date & Time	19 MAR 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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

22 MAR 2021 05:27:49

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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

29 MAR 2021 17:38:19

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	05 APR 2021 05:18:18
Patient Cloud Open Date & Time	05 APR 2021 00:01
Patient Cloud Close Date & Time	09 APR 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 APR 2021 21:04:18
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	True
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	19 APR 2021 05:14:03
Patient Cloud Open Date & Time	19 APR 2021 00:01
Patient Cloud Close Date & Time	23 APR 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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

28 APR 2021 08:16:00

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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07 MAY 2021 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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21 MAY 2021 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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24 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAY 2021 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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04 JUN 2021 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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18 JUN 2021 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

02 JUL 2021 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUL 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUL 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

26 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 JUL 2021 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Open Date & Time](#)

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02 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 AUG 2021 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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="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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

13 AUG 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	06 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 SEP 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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°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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 SEP 2021 23:59



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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24 SEP 2021 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

08 OCT 2021 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 OCT 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 OCT 2021 23:59
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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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°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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Open Date & Time](#)

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01 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 NOV 2021 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

[Patient Cloud Close Date & Time](#)

12 NOV 2021 23:59



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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03 DEC 2021 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

06 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 DEC 2021 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

17 DEC 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2021 23:59
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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2021 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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07 JAN 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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14 JAN 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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21 JAN 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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28 JAN 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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04 FEB 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

11 FEB 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Open Date & Time](#)

14 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 FEB 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

25 FEB 2022 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2022 23:59



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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11 MAR 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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18 MAR 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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25 MAR 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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01 APR 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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08 APR 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 APR 2022 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

[Patient Cloud Close Date & Time](#)

22 APR 2022 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 APR 2022 23:59



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

06 MAY 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Open Date & Time](#)

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09 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2022 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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27 MAY 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2022 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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17 JUN 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2022 23:59



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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01 JUL 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2022 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

15 JUL 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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°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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2022 23:59



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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29 JUL 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2022 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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19 AUG 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2022 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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°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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2022 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

09 SEP 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2022 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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 <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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2022 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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07 OCT 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 OCT 2022 23:59



US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

**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°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 ☐

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 OCT 2022 23:59

US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Close Date & Time](#)

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28 OCT 2022 23:59

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US3192575

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:03:43

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"/>

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2022 23:59

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**US3192575**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 11 Aug 2021 22:03:43**

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		02 MAR 2021 13:14:36

US3192575

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:28:07

Generated On: 11 Aug 2021 22:03:43

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*



US3192575

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:28:07

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192575

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3192575

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192575

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

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

US3192575

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192575

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

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

US3192575

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192575

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4



US3192575

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 MAR 2021
Time of assessment (00:00-23:59)	17:08 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 17:08
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 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)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192575

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

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.*

US3192575

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3192575

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3192575**

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

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

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*

**US3192575**

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

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3192575**

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

**Form: COVID-19 Contact**

**Generated On: 11 Aug 2021 22:03:43**

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

**US3192575**

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

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

**Generated On: 11 Aug 2021 22:03:43**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3192575

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

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3192575

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 17:59:10

Generated On: 11 Aug 2021 22:03:43

Date of updated informed consent ( <i>dd MMM yyyy</i> )	21 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> )	21 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

**US3192575**

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

**Form: Vital Signs - Dosing**

**Data signed:** (b) (4) 08 Apr 2021 01:18:01

**Generated On: 11 Aug 2021 22:03:43**

Height	67 in
Weight	153 lb
BMI (xxx.x)	24.01329

US3192575

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Height	67 in
Weight	153 lb
BMI (xxx.x)	24.01329
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)	21 JAN 2021
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 13:30
Temperature (xxx.x)	99 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3192575

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Height	67 in
Weight	153 lb
BMI (xxx.x)	24.01329
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)	21 JAN 2021
Time of assessment (00:00-23:59)	14:36 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 14:36
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3192575

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

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 JAN 2021

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

US3192575

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

Form: Pregnancy Test

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	21 JAN 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)	

US3192575

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

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 01:17:41

Generated On: 11 Aug 2021 22:03:43

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) 21 JAN 2021

What was the treatment time? (00:00-23:59) 14:05 (24 HR)

Treatment Date and Time (derived) 21 JAN 2021 14:05

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



US3192575

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 01:17:41

Generated On: 11 Aug 2021 22:03:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 JAN 2021

Collection time (00:00-23:59)

13:38 (24 HR)

Collection date and time (derived)

21 JAN 2021 13:38

US3192575

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Apr 2021 01:17:41

Generated On: 11 Aug 2021 22:03:43

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 JAN 2021
Collection time (00:00 - 23:59)	13:39
Collection Date and Time (derived)	21 JAN 2021 13:39

US3192575

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

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:17:41

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192575

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3192575

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3192575

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3192575

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 01:17:41

Generated On: 11 Aug 2021 22:03:43

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)	24 FEB 2021
Time of assessment (00:00-23:59)	15:40 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 15:40
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3192575

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 01:17:41

Generated On: 11 Aug 2021 22:03:43

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)	24 FEB 2021
Time of assessment (00:00-23:59)	16:33 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 16:33
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG



US3192575

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 FEB 2021

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

US3192575

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test ( <i>dd MMM yyyy</i> )	24 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)	

US3192575

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

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) 24 FEB 2021

What was the treatment time? (00:00-23:59) 16:03 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 16:03

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

US3192575

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192575

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3192575

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:18:01

Generated On: 11 Aug 2021 22:03:43

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192575

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 01:17:41

Generated On: 11 Aug 2021 22:03:43

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3192575

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 01:17:41

Generated On: 11 Aug 2021 22:03:43

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	24 MAR 2021
Time of assessment ( <i>00:00-23:59</i> )	17:08 (24 HR)
Vital Signs Date and Time (derived)	24 MAR 2021 17:08
Temperature ( <i>xxx.x</i> )	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	66 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3192575

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 01:17:41

Generated On: 11 Aug 2021 22:03:43

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.*

US3192575

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 01:17:41

Generated On: 11 Aug 2021 22:03:43

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 MAR 2021

Collection time (00:00-23:59)

17:14 (24 HR)

Collection date and time (derived)

24 MAR 2021 17:14

US3192575

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Mar 2021 17:15:49

Generated On: 11 Aug 2021 22:03:43

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3192575

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

AEID	
Adverse event	SORE ARM AT INJECTION SITE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	21 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3192575

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

AEID	
Adverse event	CHILLS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" 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)	24 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	26 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

AEID

Adverse event

BODY ACHES

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

24 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3192575

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

AEID

Adverse event

HEADACHE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

24 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3192575

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

AEID

Adverse event

RASH AT INJECTION SITE NON-URTICARIAL

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

25 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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US3192575

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3192575

Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

AEID

Adverse event

TENDERNESS AT INJECTION  
SITE

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

22 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

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 type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

---

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

Yes ☒

No ☐

---

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

---



US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

Name of Medication JUNEL

Prophylaxis Yes ☒  
No ☐

Indication BIRTH CONTROL

Dose per administration 1/20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

	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 JUN 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"/>

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

Name of Medication MAGNESIUM OXIDE

Prophylaxis Yes ☐  
No ☒

Indication TENSION HEADACHES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication SORENESS AT THE INJECTION  
SITE

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

	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)	27 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

Name of Medication	FLU SHOT
Prophylaxis	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Indication	FLU PREVENTION
Dose per administration	0.5
Dose unit	mg <input type="radio"/>
	ug <input type="radio"/>
	mL <input checked="" type="radio"/>
	g <input type="radio"/>
	IU <input type="radio"/>
	tablet <input type="radio"/>
	capsule <input type="radio"/>
	puff <input type="radio"/>
	Other <input type="radio"/>

If dose unit is Other, specify

Frequency	once daily <input type="radio"/>
	twice daily <input type="radio"/>
	three times daily <input type="radio"/>
	four times daily <input type="radio"/>
	every other day <input type="radio"/>
	every week <input type="radio"/>
	every month <input type="radio"/>
	as needed <input type="radio"/>
	once <input checked="" type="radio"/>
	unknown <input type="radio"/>
	other <input type="radio"/>

If frequency is Other, specify

Route of administration	Oral <input type="radio"/>
	Topical <input type="radio"/>
	Subcutaneous <input type="radio"/>
	Transdermal <input type="radio"/>
	Intraocular <input type="radio"/>

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

	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)		06 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)		06 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication TENDERNESS AT INJECTION  
SITE

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

	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)	22 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)		22 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication CHILLS, BODY ACHES AND  
HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

	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)	24 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3192575

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 01:17:40

Generated On: 11 Aug 2021 22:03:43

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3192575

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:03:43

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:03:43

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 ☐

Audit

US3192575 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)



**US3192575**

**Form: Participant Creation**

**Generated On: 11 Aug 2021 22:03:43**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'US3192575'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 18:00:37

**US3192575**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:51:21

**US3192575**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '29 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 18:00:38

US3192575

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Clinic (Clinic)'	Norma Barrientos (b) (4)	05 Sep 2020 12:51:21

**US3192575**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered 'SCRN'	System	05 Sep 2020 12:51:21

US3192575

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:43

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered (b) (6) 1990'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 18:00:40

**US3192575**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:03:43**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '30'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:33

**US3192575**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:03:43**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered 'YEARS'	System	03 Sep 2020 00:10:33



**US3192575**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:03:43**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered '30'	System	29 Aug 2020 18:32:31

**US3192575**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:03:43**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Female (F)'	(b) (4) Norma Barrientos (b) (4)	03 Sep 2020 00:10:33

US3192575

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:03:43

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Norma Barrientos (b) (4)	03 Sep 2020 00:10:33

**US3192575**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:03:43**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'I'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:33

**US3192575**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:03:43**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:33

**US3192575**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:03:43**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:33

**US3192575**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:03:43**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:33

**US3192575**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:03:43**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:33



**US3192575**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:03:43**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:33

**US3192575**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:03:43**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	(b) (4) Norma Barrientos (b) (4)	03 Sep 2020 00:10:33

**US3192575**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:03:43**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:33

**US3192575**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Aug 2021 22:03:43**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:33

**US3192575**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:03:43**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '29 Aug 2020'	Zoe Sesma (b) (4)	29 Aug 2020 18:32:31

**US3192575**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered 'Aug 2020'	System	29 Aug 2020 18:32:31

**US3192575**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered '2020'	System	29 Aug 2020 18:32:31

**US3192575**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:03:43**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Amendment 3 (3)'	Zoe Sesma (b) (4)	29 Aug 2020 18:32:31



**US3192575**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	29 Aug 2020 18:32:31

**US3192575**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:03:43**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Zoe Sesma (b) (4)	29 Aug 2020 18:32:31

**US3192575**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:03:43**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Zoe Sesma (b) (4)	29 Aug 2020 18:32:31

**US3192575**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:03:43**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Zoe Sesma (b) (4)	29 Aug 2020 18:32:31

**US3192575**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:03:43**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 18:00:38

**US3192575**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Aug 2021 22:03:43**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered 'I'	System	29 Aug 2020 18:32:36

**US3192575**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	29 Aug 2020 18:32:36

**US3192575**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 11 Aug 2021 22:03:43**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:55:02



US3192575

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:03:43

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Tension headache, LLT: Tension headaches - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 12:56:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 12:56:37
Data point term sent to Coder	System	05 Sep 2020 12:55:54
User entered 'TENSION HEADACHES'	Norma Barrientos (b) (4)	05 Sep 2020 12:55:26

**US3192575**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'UN UNK 2010'	Norma Barrientos (b) (4)	05 Sep 2020 12:55:26

**US3192575**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	05 Sep 2020 12:55:26

**US3192575**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	05 Sep 2020 12:55:26

**US3192575**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:55:26

**US3192575**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	05 Sep 2020 12:55:26

**US3192575**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered 'Jan 2010'	System	05 Sep 2020 12:55:26

**US3192575**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered '2010'	System	05 Sep 2020 12:55:26



**US3192575**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered empty.	System	05 Sep 2020 12:55:26

**US3192575**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered empty.	System	05 Sep 2020 12:55:26

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:53:28

US3192575

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:43

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	05 Sep 2020 12:54:04
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	05 Sep 2020 12:54:04
User closed query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	05 Sep 2020 12:54:04
Query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' answered by data change (Site from System).	System	05 Sep 2020 12:54:04
User closed query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	05 Sep 2020 12:54:04
User entered '29 Aug 2020' reason for change: Data Entry Error	Norma Barrientos (b) (4)	05 Sep 2020 12:54:04
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	05 Sep 2020 12:53:28
User opened query 'The Assessment Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	05 Sep 2020 12:53:28
User opened query 'Screening Vital Signs is not within 28 days of Visit 1. Please reconcile or confirm dates.' (Site from System).	System	05 Sep 2020 12:53:28
User entered '29 Aug 2002'	Norma Barrientos (b) (4)	05 Sep 2020 12:53:28

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '10:45'	Norma Barrientos (b) (4)	05 Sep 2020 12:53:28

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered '29 Aug 2020 10:45'	System	05 Sep 2020 12:54:04
User entered '29 Aug 2002 10:45'	System	05 Sep 2020 12:53:28

US3192575

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '67' in	(b) (4)	
	Norma Barrientos (b) (4)	05 Sep 2020 12:53:28
DataPoint set to visible.	(b) (4)	
	System	29 Aug 2020 18:32:36

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '154.6' lb	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:53:28
DataPoint set to visible.	(b) (4) System	29 Aug 2020 18:32:36



US3192575

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:43

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered '24.26441'	System	05 Sep 2020 12:53:28
DataPoint set to visible.	System	29 Aug 2020 18:32:36

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered 'kg/m2'	System	05 Sep 2020 12:53:28
DataPoint set to visible.	System	29 Aug 2020 18:32:36

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered missing code ND - Not Done.	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:53:28

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	(b) (4)	
	Norma Barrientos (b) (4)	05 Sep 2020 12:53:28
	(b) (4)	

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	(b) (4)	
	Norma Barrientos (b) (4)	05 Sep 2020 12:53:28
	(b) (4)	

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered missing code ND - Not Done.	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:53:28

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered 'bpm'	System	05 Sep 2020 12:53:28

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered missing code ND - Not Done.	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:53:28



US3192575

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered 'breaths/min'	System	05 Sep 2020 12:53:28

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered missing code ND - Not Done.	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:53:28

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered 'mmHg'	System	05 Sep 2020 12:53:28

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered missing code ND - Not Done.	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:53:28

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered 'mmHg'	System	05 Sep 2020 12:53:28

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55

**US3192575**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55

**US3192575**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:03:43**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:51:44



**US3192575**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:03:43**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '29 Aug 2020'	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:51:44

**US3192575**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:03:43**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '29 Aug 2020'	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:52:26

US3192575

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:03:43

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:52:26

**US3192575**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:03:43**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:52:26

**US3192575**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:03:43**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:52:26

US3192575

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:52:26

**US3192575**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:03:43**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	05 Sep 2020 12:52:26

US3192575

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:52:26



**US3192575**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 11 Aug 2021 22:03:43**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	05 Sep 2020 12:52:26

**US3192575**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	05 Sep 2020 12:54:44

**US3192575**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

**Date of test** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '29 Aug 2020'	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:54:44

**US3192575**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Urine (URINE)'	Norma Barrientos (b) (4)	05 Sep 2020 12:54:44

**US3192575**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Negative (NEGATIVE)'	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:54:44

**US3192575**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	(b) (4)	
	Norma Barrientos (b) (4)	05 Sep 2020 12:54:44
	(b) (4)	

**US3192575**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '29 Aug 2020'	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 12:54:44

**US3192575**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '11:05'	Norma Barrientos (b) (4)	05 Sep 2020 12:54:44



**US3192575**

**Folder: Screening**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User entered '29 Aug 2020 11:05'	System	05 Sep 2020 12:54:44

US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	(b) (4) Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	(b) (4) Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	(b) (4) Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09



US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	(b) (4) Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

**US3192575**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:03:43**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	(b) (4)	
	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	(b) (4)	
	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09
	(b) (4)	

**US3192575**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:03:43**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	(b) (4) Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09



US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'I'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

**US3192575**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 11 Aug 2021 22:03:43**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '0'	Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

US3192575

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:03:43

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:31:55
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	(b) (4) Norma Barrientos (b) (4)	03 Sep 2020 00:10:09

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	05 Sep 2020 12:50:59

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '29 Aug 2020'	Norma Barrientos (b) (4)	05 Sep 2020 12:50:59



**US3192575**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Clinic (Clinic)'	Norma Barrientos (b) (4)	05 Sep 2020 12:50:59

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'VISIT1'	System	05 Sep 2020 12:50:59

US3192575

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '29 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 18:25:33

US3192575

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '109983'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 18:25:33

US3192575

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Aug 2020 18:25:33

US3192575

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:43

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User closed query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Sep 2020 19:42:16
Query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' answered with 'no' (Site from DM).	Norma Barrientos (b) (4)	03 Sep 2020 00:09:22
User entered 'No (N)'	Norma Barrientos (b) (4)	03 Sep 2020 00:09:16
User opened query 'PER CDM: Please complete this section of the form. A required response (Yes or No) is needed for each.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Aug 2020 15:33:20

US3192575

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:43

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Norma Barrientos (b) (4)	03 Sep 2020 00:09:16

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Norma Barrientos (b) (4)	03 Sep 2020 00:09:16



**US3192575**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:03:43**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Norma Barrientos (b) (4)	03 Sep 2020 00:09:16

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 11 Aug 2021 22:03:43**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Norma Barrientos (b) (4)	03 Sep 2020 00:09:16

US3192575

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:03:43

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:16:08
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Field completed' (Site from DM).	Saysamone Banks (b) (4)	02 Dec 2020 17:13:26
User entered 'No (N)'	Saysamone Banks (b) (4)	02 Dec 2020 17:13:22
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 23:12:26
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:38:13
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:38:12

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:03:43**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered missing code ND - Not Done.	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:03:43**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered missing code ND - Not Done.	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

US3192575

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:03:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered missing code ND - Not Done.	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:03:43**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered missing code ND - Not Done.	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

US3192575

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User accepted default value 'Pre-Dose (PREDOSE)'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51
	(b) (4)	



US3192575

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

US3192575

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '29 Aug 2020'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '10:45'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered '29 Aug 2020 10:45'	System	05 Sep 2020 12:59:51

US3192575

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User closed query 'Temperature reported is out of range < 36C (96.8 F) 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)	30 Sep 2020 00:11:52
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'per PI, NCS' (Site from System).	Yvonne De Los Reyes (b) (4)	18 Sep 2020 16:11:39
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:11:14
User entered '96.3' F	Norma Barrientos (b) (4) (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Oral (Oral)'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '62'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51



**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'bpm'	System	05 Sep 2020 12:59:51

US3192575

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '16'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

US3192575

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:43

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'breaths/min'	System	05 Sep 2020 12:59:51

US3192575

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '96'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

US3192575

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:43

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'mmHg'	System	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '75'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'mmHg'	System	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:03:43**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered missing code ND - Not Done.	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51



**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:03:43**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered missing code ND - Not Done.	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

US3192575

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User accepted default value 'Post-Dose (POSTDOSE)'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

US3192575

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

US3192575

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '29 Aug 2020'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '11:58'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered '29 Aug 2020 11:58'	System	05 Sep 2020 12:59:51

US3192575

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '97.6' F	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Oral (Oral)'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51



**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '56'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'bpm'	System	05 Sep 2020 12:59:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '12'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'breaths/min'	System	05 Sep 2020 12:59:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '102'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'mmHg'	System	05 Sep 2020 12:59:51

US3192575

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '68'	Norma Barrientos (b) (4)	05 Sep 2020 12:59:51



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'mmHg'	System	05 Sep 2020 12:59:51

US3192575

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:03:43

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Norma Barrientos (b) (4)	05 Sep 2020 12:50:43

US3192575

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:03:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:50:43

US3192575

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:03:43

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test and FSH sample data should be removed from this page. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Sep 2020 15:46:14
Query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test and FSH sample data should be removed from this page. Please update accordingly.' answered with 'corrected' (Site from DM).	Cynthia Montgomery (b) (4)	11 Sep 2020 01:58:29
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 01:58:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 01:58:18
User entered 'No (N)' reason for change: Data Entry Error	Cynthia Montgomery (b) (4)	11 Sep 2020 01:58:18
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 01:57:54
User entered empty; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	11 Sep 2020 01:57:54
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and VID1 occur on the same day, the corresponding field should be marked as "No" and pregnancy test and FSH sample data should be removed from this page. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 16:39:09
User entered 'Yes (Y)'	Norma Barrientos (b) (4) (b) (4)	05 Sep 2020 13:00:16

US3192575

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:03:43

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	11 Sep 2020 01:57:54
User entered '29 Aug 2020'	Norma Barrientos (b) (4)	05 Sep 2020 13:00:16

US3192575

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:03:43

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty; reason for change Data Entry Error	(b) (4) Cynthia Montgomery	11 Sep 2020 01:57:54
User entered 'Urine (URINE)'	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 13:00:16

US3192575

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:03:43

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty; reason for change Data Entry Error	(b) (4) Cynthia Montgomery	11 Sep 2020 01:57:54
User entered 'Negative (NEGATIVE)'	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 13:00:16

US3192575

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:03:43

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User closed query 'Per CDM: Screening and V1D1 have occurred on a same day. Please consider to mark response for Was FSH sample collected? as No' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Sep 2020 15:31:29
Query 'Per CDM: Screening and V1D1 have occurred on a same day. Please consider to mark response for Was FSH sample collected? as No' answered with 'updated' (Site from DM).	Yvonne De Los Reyes (b) (4)	18 Sep 2020 03:56:11
User entered 'No (N)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	18 Sep 2020 03:56:08
User opened query 'Per CDM: Screening and V1D1 have occurred on a same day. Please consider to mark response for Was FSH sample collected? as No' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 15:47:09
User entered empty; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	11 Sep 2020 01:57:54
User entered 'No (N)'	Norma Barrientos (b) (4) (b) (4)	05 Sep 2020 13:00:16



**US3192575**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty; reason for change Data Entry Error	Cynthia Montgomery (b) (4)	11 Sep 2020 01:57:54
User entered '29 Aug 2020'	Norma Barrientos (b) (4)	05 Sep 2020 13:00:16

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty; reason for change Data Entry Error	(b) (4) Cynthia Montgomery	11 Sep 2020 01:57:54
User entered '11:05'	(b) (4) Norma Barrientos (b) (4)	05 Sep 2020 13:00:16

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered empty.	System	11 Sep 2020 01:57:54
User entered '29 Aug 2020 11:05'	System	05 Sep 2020 13:00:16

US3192575

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	29 Aug 2020 18:33:00

US3192575

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Zoe Sesma (b) (4)	29 Aug 2020 18:33:00

US3192575

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Zoe Sesma (b) (4)	29 Aug 2020 18:33:00

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered 'MRNA-1273 OR PLACEBO'	System	29 Aug 2020 18:33:00

US3192575

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '29 Aug 2020'	Zoe Sesma (b) (4)	29 Aug 2020 18:33:00



US3192575

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '11:26'	Zoe Sesma (b) (4)	29 Aug 2020 18:33:00

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered '29 Aug 2020 11:26'	System	29 Aug 2020 18:33:00

US3192575

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Left Arm (LEFT ARM)'	Zoe Sesma (b) (4)	29 Aug 2020 18:33:00

US3192575

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered 'ONCE'	System	29 Aug 2020 18:33:00

US3192575

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered 'INTRAMUSCULAR'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	05 Sep 2020 12:50:16

US3192575

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '29 Aug 2020'	Norma Barrientos (b) (4)	05 Sep 2020 12:50:16

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '11:15'	Norma Barrientos (b) (4)	05 Sep 2020 12:50:16



**US3192575**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered '29 Aug 2020 11:15'	System	05 Sep 2020 12:50:16

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Aug 2021 22:03:43**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '29 Aug 2020'	Norma Barrientos (b) (4)	05 Sep 2020 12:50:35

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Norma Barrientos (b) (4)	05 Sep 2020 12:50:35

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	05 Sep 2020 12:50:35

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '11:11'	Norma Barrientos (b) (4)	05 Sep 2020 12:50:35

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered '29 Aug 2020 11:11'	System	05 Sep 2020 12:50:35

US3192575

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:03:43

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Norma Barrientos (b) (4)	05 Sep 2020 12:50:35

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Norma Barrientos (b) (4)	05 Sep 2020 12:50:35



**US3192575**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:03:43**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:50:35

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered empty.	System	05 Sep 2020 12:50:35

US3192575

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:03:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	05 Sep 2020 12:49:58

**US3192575**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered 'I'	System	05 Sep 2020 12:49:58

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:52:37', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '545e2cd3-8046-496d-936b-0132dd3d2212' User entered 'Yes (Y)'	System	29 Aug 2020 18:54:20
	System	29 Aug 2020 18:54:20

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:54:07', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '545e2cd3-8046-496d-936b-0132dd3d2212' User entered '97.6'	System	29 Aug 2020 18:54:20
	System	29 Aug 2020 18:54:20

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:54:10', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '545e2cd3-8046-496d-936b-0132dd3d2212'	System	29 Aug 2020 18:54:20
User entered 'No (N)'	System	29 Aug 2020 18:54:20



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:54:16', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '545e2cd3-8046-496d-936b-0132dd3d2212'	System	29 Aug 2020 18:54:20
User entered '29 Aug 2020 11:54'	System	29 Aug 2020 18:54:20

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Aug 2020 11:46'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Aug 2020 14:16'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:53:19', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c4cb6cfc-19a7-4990-8c6f-d7c07e1d5d22'	System	30 Aug 2020 03:54:17
User entered 'Yes (Y)'	System	30 Aug 2020 03:54:17

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:54:03', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c4cb6cfc-19a7-4990-8c6f-d7c07e1d5d22'	System	30 Aug 2020 03:54:17
User entered '96.8'	System	30 Aug 2020 03:54:17

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:54:10', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c4cb6cfc-19a7-4990-8c6f-d7c07e1d5d22'	System	30 Aug 2020 03:54:17
User entered 'No (N)'	System	30 Aug 2020 03:54:17

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:54:15', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c4cb6cfc-19a7-4990-8c6f-d7c07e1d5d22'	System	30 Aug 2020 03:54:17
User entered '29 Aug 2020 20:54'	System	30 Aug 2020 03:54:17



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Aug 2020 15:11'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 2'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:30:51', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '166e7e7a-5acf-44a9-a623-c6d766fb9022' User entered 'Yes (Y)'	System	31 Aug 2020 01:31:06
	System	31 Aug 2020 01:31:06

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:30:55', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '166e7e7a-5acf-44a9-a623-c6d766fb9022' User entered '95.5'	System	31 Aug 2020 01:31:06
	System	31 Aug 2020 01:31:06

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:30:58', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '166e7e7a-5acf-44a9-a623-c6d766fb9022'	System	31 Aug 2020 01:31:06
User entered 'No (N)'	System	31 Aug 2020 01:31:06

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:31:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '166e7e7a-5acf-44a9-a623-c6d766fb9022'	System	31 Aug 2020 01:31:06
User entered '30 Aug 2020 18:31'	System	31 Aug 2020 01:31:06

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 18:33:00



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 3'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:03:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:30:34', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6d7e084c-f20b-4504-880d-725bae8826b5' User entered 'Yes (Y)'	System	01 Sep 2020 03:31:12
	System	01 Sep 2020 03:31:12

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:30:38', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6d7e084c-f20b-4504-880d-725bae8826b5' User entered '97.2'	System	01 Sep 2020 03:31:12
	System	01 Sep 2020 03:31:12

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:30:41', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6d7e084c-f20b-4504-880d-725bae8826b5' User entered 'No (N)'	System	01 Sep 2020 03:31:12
	System	01 Sep 2020 03:31:12

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:30:47', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6d7e084c-f20b-4504-880d-725bae8826b5' User entered '31 Aug 2020 20:30'	System	01 Sep 2020 03:31:12
	System	01 Sep 2020 03:31:12

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 18:33:00



US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 4'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:03:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:48', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '8f06a5e7-ae6e-4c95-803e-3eaf889b4ce2' User entered 'Yes (Y)'	System	02 Sep 2020 01:19:08
	System	02 Sep 2020 01:19:08

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:52', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '8f06a5e7-ae6e-4c95-803e-3eaf889b4ce2' User entered '95.5'	System	02 Sep 2020 01:19:08
	System	02 Sep 2020 01:19:08

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:56', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '8f06a5e7-ae6e-4c95-803e-3eaf889b4ce2'	System	02 Sep 2020 01:19:08
User entered 'Yes (Y)'	System	02 Sep 2020 01:19:08

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient took ibuprofen 200mgs 3tabs 600mgs for the whole day due to pain' (Site from System).		29 Sep 2020 14:17:19
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:19:01', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '8f06a5e7-ae6e-4c95-803e-3eaf889b4ce2' User entered '1'	maggie Tono (b) (4) (b) (4)	24 Sep 2020 22:43:52
	System	02 Sep 2020 01:19:08
	System	02 Sep 2020 01:19:08
	System	02 Sep 2020 01:19:08

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:03:43

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:19:01', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '8f06a5e7-ae6e-4c95-803e-3eaf889b4ce2' User entered '0'	System	02 Sep 2020 01:19:08
	System	02 Sep 2020 01:19:08

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:19:05', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '8f06a5e7-ae6e-4c95-803e-3eaf889b4ce2'	System	02 Sep 2020 01:19:08
User entered '01 Sep 2020 18:19'	System	02 Sep 2020 01:19:08

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 18:33:00



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 5'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:16:55', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17d5308b-ccb0-4f8e-a08b-4a98a43a0498' User entered 'Yes (Y)'	System	03 Sep 2020 12:17:10
	System	03 Sep 2020 12:17:10

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:16:59', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17d5308b-ccb0-4f8e-a08b-4a98a43a0498' User entered '97.2'	System	03 Sep 2020 12:17:10
	System	03 Sep 2020 12:17:10

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:01', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17d5308b-ccb0-4f8e-a08b-4a98a43a0498'	System	03 Sep 2020 12:17:10
User entered 'Yes (Y)'	System	03 Sep 2020 12:17:10

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'patient took ibuprofen 600mgs 2tabs' (Site from System).	(b) (4)	05 Oct 2020 03:47:47
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.'	maggie Tono (b) (4)	01 Oct 2020 16:56:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:04', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17d5308b-ccb0-4f8e-a08b-4a98a43a0498'	System	03 Sep 2020 12:17:10
User entered '1'	System	03 Sep 2020 12:17:10

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:03:43

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:04', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17d5308b-ccb0-4f8e-a08b-4a98a43a0498' User entered '0'	System	03 Sep 2020 12:17:10
	System	03 Sep 2020 12:17:10

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:06', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17d5308b-ccb0-4f8e-a08b-4a98a43a0498' User entered '03 Sep 2020 05:17'	System	03 Sep 2020 12:17:10
	System	03 Sep 2020 12:17:10



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 6'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:03:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:58:30', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '888a29a4-40b9-4138-bcc4-d5d89c4a6c97' User entered 'Yes (Y)'	System	04 Sep 2020 03:58:42
	System	04 Sep 2020 03:58:42

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:58:34', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '888a29a4-40b9-4138-bcc4-d5d89c4a6c97' User entered '97.5'	System	04 Sep 2020 03:58:42
	System	04 Sep 2020 03:58:42

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:58:37', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '888a29a4-40b9-4138-bcc4-d5d89c4a6c97' User entered 'No (N)'	System	04 Sep 2020 03:58:42
	System	04 Sep 2020 03:58:42

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:58:39', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '888a29a4-40b9-4138-bcc4-d5d89c4a6c97' User entered '03 Sep 2020 20:58'	System	04 Sep 2020 03:58:42
	System	04 Sep 2020 03:58:42

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 18:33:00



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 7'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:35:27', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '004f7fe3-a1a3-409d-bb1d-bd9df1df67e9' User entered 'Yes (Y)'	System	05 Sep 2020 04:35:43
	System	05 Sep 2020 04:35:43

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:35:32', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '004f7fe3-a1a3-409d-bb1d-bd9df1df67e9' User entered '97.2'	System	05 Sep 2020 04:35:43
	System	05 Sep 2020 04:35:43

US3192575

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:35:35', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '004f7fe3-a1a3-409d-bb1d-bd9df1df67e9' User entered 'No (N)'	System	05 Sep 2020 04:35:43
	System	05 Sep 2020 04:35:43

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:35:38', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '004f7fe3-a1a3-409d-bb1d-bd9df1df67e9' User entered '04 Sep 2020 21:35'	System	05 Sep 2020 04:35:43
	System	05 Sep 2020 04:35:43

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 18:33:00



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:54:26', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '5dc6dbc5-8b38-4e4e-a4b1-df03062cb471'	System	29 Aug 2020 18:54:57
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 18:54:57

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:54:38', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '5dc6dbc5-8b38-4e4e-a4b1-df03062cb471' User entered 'No (N)'	System	29 Aug 2020 18:54:57
	System	29 Aug 2020 18:54:57

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:54:44', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '5dc6dbc5-8b38-4e4e-a4b1-df03062cb471' User entered 'No (N)'	System	29 Aug 2020 18:54:57
	System	29 Aug 2020 18:54:57

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:54:49', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '5dc6dbc5-8b38-4e4e-a4b1-df03062cb471' User entered 'None (1)'	System	29 Aug 2020 18:54:57

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:54:52', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '5dc6dbc5-8b38-4e4e-a4b1-df03062cb471' User entered '29 Aug 2020 11:54'	System	29 Aug 2020 18:54:57
	System	29 Aug 2020 18:54:57

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Aug 2020 11:46'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Aug 2020 14:16'	System	29 Aug 2020 18:33:00



US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:54:37', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '1843451f-1203-4e00-8f88-ff639b95ca6b' User entered 'None (1)'	System	30 Aug 2020 03:55:08
	System	30 Aug 2020 03:55:08

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:54:41', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '1843451f-1203-4e00-8f88-ff639b95ca6b' User entered 'No (N)'	System	30 Aug 2020 03:55:08
	System	30 Aug 2020 03:55:08

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:54:54', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '1843451f-1203-4e00-8f88-ff639b95ca6b' User entered 'No (N)'	System	30 Aug 2020 03:55:08
	System	30 Aug 2020 03:55:08

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:55:02', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '1843451f-1203-4e00-8f88-ff639b95ca6b' User entered 'None (1)'	System	30 Aug 2020 03:55:08
	System	30 Aug 2020 03:55:08

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:55:06', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '1843451f-1203-4e00-8f88-ff639b95ca6b' User entered '29 Aug 2020 20:55'	System	30 Aug 2020 03:55:08
	System	30 Aug 2020 03:55:08

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Aug 2020 15:11'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 18:33:00



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 2'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:30:24', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6ad78ec1-55f7-4467-bebe-d2a35cb4f950'	System	31 Aug 2020 01:30:45
User entered 'Does not interfere with activity (2)'	System	31 Aug 2020 01:30:45

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:30:28', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6ad78ec1-55f7-4467-bebe-d2a35cb4f950' User entered 'No (N)'	System	31 Aug 2020 01:30:45
	System	31 Aug 2020 01:30:45

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:30:34', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6ad78ec1-55f7-4467-bebe-d2a35cb4f950' User entered 'No (N)'	System	31 Aug 2020 01:30:45
	System	31 Aug 2020 01:30:45

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:30:40', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6ad78ec1-55f7-4467-bebe-d2a35cb4f950' User entered 'None (1)'	System	31 Aug 2020 01:30:45
	System	31 Aug 2020 01:30:45

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:30:42', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6ad78ec1-55f7-4467-bebe-d2a35cb4f950' User entered '30 Aug 2020 18:30'	System	31 Aug 2020 01:30:45
	System	31 Aug 2020 01:30:45

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 18:33:00



US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 3'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:30:55', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '402b9ddb-320d-4419-bbcc-bc0eb9bb2084'	System	01 Sep 2020 03:31:19
User entered 'Does not interfere with activity (2)'	System	01 Sep 2020 03:31:19

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:03:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:30:57', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '402b9ddb-320d-4419-bbcc-bc0eb9bb2084' User entered 'No (N)'	System	01 Sep 2020 03:31:19
	System	01 Sep 2020 03:31:19

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:31:03', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '402b9ddb-320d-4419-bbcc-bc0eb9bb2084' User entered 'No (N)'	System	01 Sep 2020 03:31:19
	System	01 Sep 2020 03:31:19

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:31:09', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '402b9ddb-320d-4419-bbcc-bc0eb9bb2084'	System	01 Sep 2020 03:31:19
User entered 'None (1)'	System	01 Sep 2020 03:31:19

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:31:12', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '402b9ddb-320d-4419-bbcc-bc0eb9bb2084'	System	01 Sep 2020 03:31:19
User entered '31 Aug 2020 20:31'	System	01 Sep 2020 03:31:19

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 18:33:00



US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 4'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:28', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '9dd0c6c4-b089-4bbf-905a-528f8b2130bd' User entered 'None (1)'	System	02 Sep 2020 01:18:47
	System	02 Sep 2020 01:18:47

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:03:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:31', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '9dd0c6c4-b089-4bbf-905a-528f8b2130bd' User entered 'No (N)'	System	02 Sep 2020 01:18:47
	System	02 Sep 2020 01:18:47

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:33', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '9dd0c6c4-b089-4bbf-905a-528f8b2130bd' User entered 'No (N)'	System	02 Sep 2020 01:18:47
	System	02 Sep 2020 01:18:47

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:39', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '9dd0c6c4-b089-4bbf-905a-528f8b2130bd' User entered 'None (1)'	System	02 Sep 2020 01:18:47
	System	02 Sep 2020 01:18:47

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:43', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '9dd0c6c4-b089-4bbf-905a-528f8b2130bd' User entered '01 Sep 2020 18:18'	System	02 Sep 2020 01:18:47
	System	02 Sep 2020 01:18:47

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 18:33:00



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 5'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:10', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd3f49320-2b46-4edc-8004-b4d2fda115d0' User entered 'None (1)'	System	03 Sep 2020 12:17:33
	System	03 Sep 2020 12:17:33

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:13', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd3f49320-2b46-4edc-8004-b4d2fda115d0'	System	03 Sep 2020 12:17:33
User entered 'No (N)'	System	03 Sep 2020 12:17:33

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:17', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd3f49320-2b46-4edc-8004-b4d2fda115d0' User entered 'No (N)'	System	03 Sep 2020 12:17:33
	System	03 Sep 2020 12:17:33

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:25', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd3f49320-2b46-4edc-8004-b4d2fda115d0' User entered 'None (1)'	System	03 Sep 2020 12:17:33
	System	03 Sep 2020 12:17:33

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:27', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd3f49320-2b46-4edc-8004-b4d2fda115d0' User entered '03 Sep 2020 05:17'	System	03 Sep 2020 12:17:33
	System	03 Sep 2020 12:17:33

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 18:33:00



US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 6'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:58:43', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'dc216bc4-dce2-48f4-b438-bdd2521e4cba' User entered 'None (1)'	System	04 Sep 2020 03:59:11
	System	04 Sep 2020 03:59:11

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:03:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:58:45', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'dc216bc4-dce2-48f4-b438-bdd2521e4cba' User entered 'No (N)'	System	04 Sep 2020 03:59:11
	System	04 Sep 2020 03:59:11

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:58:47', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'dc216bc4-dce2-48f4-b438-bdd2521e4cba' User entered 'No (N)'	System	04 Sep 2020 03:59:11
	System	04 Sep 2020 03:59:11

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:59:06', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'dc216bc4-dce2-48f4-b438-bdd2521e4cba' User entered 'None (1)'	System	04 Sep 2020 03:59:11
	System	04 Sep 2020 03:59:11

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:59:09', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'dc216bc4-dce2-48f4-b438-bdd2521e4cba' User entered '03 Sep 2020 20:59'	System	04 Sep 2020 03:59:11
	System	04 Sep 2020 03:59:11

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 18:33:00



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 7'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:35:44', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12b40acc-b1f8-4b84-b434-4e1a706021a2'	System	05 Sep 2020 04:35:57
User entered 'None (1)'	System	05 Sep 2020 04:35:57

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:35:46', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12b40acc-b1f8-4b84-b434-4e1a706021a2' User entered 'No (N)'	System	05 Sep 2020 04:35:57
	System	05 Sep 2020 04:35:57

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:35:48', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12b40acc-b1f8-4b84-b434-4e1a706021a2' User entered 'No (N)'	System	05 Sep 2020 04:35:57
	System	05 Sep 2020 04:35:57

US3192575

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:35:51', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12b40acc-b1f8-4b84-b434-4e1a706021a2' User entered 'None (1)'	System	05 Sep 2020 04:35:57
	System	05 Sep 2020 04:35:57

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:35:53', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12b40acc-b1f8-4b84-b434-4e1a706021a2' User entered '04 Sep 2020 21:35'	System	05 Sep 2020 04:35:57
	System	05 Sep 2020 04:35:57

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 18:33:00



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:54:57', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12bd2086-48eb-465c-a790-bfe312818956' User entered 'None (0)'	System	29 Aug 2020 18:55:22
	System	29 Aug 2020 18:55:22

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:55:03', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12bd2086-48eb-465c-a790-bfe312818956' User entered 'None (0)'	System	29 Aug 2020 18:55:22
	System	29 Aug 2020 18:55:22

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:55:05', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12bd2086-48eb-465c-a790-bfe312818956' User entered 'None (0)'	System	29 Aug 2020 18:55:22
	System	29 Aug 2020 18:55:22

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:55:09', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12bd2086-48eb-465c-a790-bfe312818956' User entered 'None (0)'	System	29 Aug 2020 18:55:22
	System	29 Aug 2020 18:55:22

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:55:11', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12bd2086-48eb-465c-a790-bfe312818956' User entered 'None (0)'	System	29 Aug 2020 18:55:22
	System	29 Aug 2020 18:55:22

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:55:14', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12bd2086-48eb-465c-a790-bfe312818956' User entered 'None (0)'	System	29 Aug 2020 18:55:22
	System	29 Aug 2020 18:55:22

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:55:17', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12bd2086-48eb-465c-a790-bfe312818956' User entered 'No (N)'	System	29 Aug 2020 18:55:22
	System	29 Aug 2020 18:55:22



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T11:55:20', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12bd2086-48eb-465c-a790-bfe312818956' User entered '29 Aug 2020 11:55'	System	29 Aug 2020 18:55:22
	System	29 Aug 2020 18:55:22

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Aug 2020 11:46'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Aug 2020 14:16'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 1, after vaccination (at home)'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:55:13', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17fcc755-1573-499e-9f17-1654a1ca0363' User entered 'None (0)'	System	30 Aug 2020 03:55:43
	System	30 Aug 2020 03:55:43

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:55:15', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17fcc755-1573-499e-9f17-1654a1ca0363' User entered 'None (0)'	System	30 Aug 2020 03:55:43
	System	30 Aug 2020 03:55:43

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:55:17', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17fcc755-1573-499e-9f17-1654a1ca0363' User entered 'None (0)'	System	30 Aug 2020 03:55:43
	System	30 Aug 2020 03:55:43

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:55:28', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17fcc755-1573-499e-9f17-1654a1ca0363' User entered 'None (0)'	System	30 Aug 2020 03:55:43
	System	30 Aug 2020 03:55:43



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:55:31', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17fcc755-1573-499e-9f17-1654a1ca0363' User entered 'None (0)'	System	30 Aug 2020 03:55:43
	System	30 Aug 2020 03:55:43

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:55:33', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17fcc755-1573-499e-9f17-1654a1ca0363' User entered 'None (0)'	System	30 Aug 2020 03:55:43
	System	30 Aug 2020 03:55:43

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:55:37', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17fcc755-1573-499e-9f17-1654a1ca0363'	System	30 Aug 2020 03:55:43
User entered 'No (N)'	System	30 Aug 2020 03:55:43

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-29T20:55:41', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17fcc755-1573-499e-9f17-1654a1ca0363' User entered '29 Aug 2020 20:55'	System	30 Aug 2020 03:55:43
	System	30 Aug 2020 03:55:43

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Aug 2020 15:11'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '30 Aug 2020 11:59'	System	29 Aug 2020 18:33:00

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 2'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:31:06', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f0a0aee3-12d9-4305-aa6c-3b90a8cf9057' User entered 'None (0)'	System	31 Aug 2020 01:31:23
	System	31 Aug 2020 01:31:23



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:31:09', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f0a0aee3-12d9-4305-aa6c-3b90a8cf9057' User entered 'None (0)'	System	31 Aug 2020 01:31:23
	System	31 Aug 2020 01:31:23

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:31:11', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f0a0aee3-12d9-4305-aa6c-3b90a8cf9057' User entered 'None (0)'	System	31 Aug 2020 01:31:23
	System	31 Aug 2020 01:31:23

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:03:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:31:13', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f0a0aee3-12d9-4305-aa6c-3b90a8cf9057' User entered 'None (0)'	System	31 Aug 2020 01:31:23
	System	31 Aug 2020 01:31:23

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:31:14', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f0a0aee3-12d9-4305-aa6c-3b90a8cf9057' User entered 'None (0)'	System	31 Aug 2020 01:31:23
	System	31 Aug 2020 01:31:23

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:31:16', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f0a0aee3-12d9-4305-aa6c-3b90a8cf9057' User entered 'None (0)'	System	31 Aug 2020 01:31:23
	System	31 Aug 2020 01:31:23

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:31:18', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f0a0aee3-12d9-4305-aa6c-3b90a8cf9057'	System	31 Aug 2020 01:31:23
User entered 'No (N)'	System	31 Aug 2020 01:31:23

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-30T18:31:20', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f0a0aee3-12d9-4305-aa6c-3b90a8cf9057'	System	31 Aug 2020 01:31:23
User entered '30 Aug 2020 18:31'	System	31 Aug 2020 01:31:23

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '30 Aug 2020 12:00'	System	29 Aug 2020 18:33:00



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '31 Aug 2020 11:59'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 3'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:31:15', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '31742b96-30b3-4331-a1e3-ea037881be3f' User entered 'None (0)'	System	01 Sep 2020 03:31:40
	System	01 Sep 2020 03:31:40

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:31:18', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '31742b96-30b3-4331-a1e3-ea037881be3f' User entered 'None (0)'	System	01 Sep 2020 03:31:40
	System	01 Sep 2020 03:31:40

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:03:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:31:21', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '31742b96-30b3-4331-a1e3-ea037881be3f' User entered 'None (0)'	System	01 Sep 2020 03:31:40
	System	01 Sep 2020 03:31:40

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:03:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:31:23', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '31742b96-30b3-4331-a1e3-ea037881be3f' User entered 'None (0)'	System	01 Sep 2020 03:31:40
	System	01 Sep 2020 03:31:40

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:31:26', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '31742b96-30b3-4331-a1e3-ea037881be3f' User entered 'None (0)'	System	01 Sep 2020 03:31:40
	System	01 Sep 2020 03:31:40

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:31:35', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '31742b96-30b3-4331-a1e3-ea037881be3f' User entered 'None (0)'	System	01 Sep 2020 03:31:40
	System	01 Sep 2020 03:31:40



US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:31:37', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '31742b96-30b3-4331-a1e3-ea037881be3f' User entered 'No (N)'	System	01 Sep 2020 03:31:40
	System	01 Sep 2020 03:31:40

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-08-31T20:31:39', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '31742b96-30b3-4331-a1e3-ea037881be3f' User entered '31 Aug 2020 20:31'	System	01 Sep 2020 03:31:40
	System	01 Sep 2020 03:31:40

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 4'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:17:56', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '75656a39-be9d-44f9-9236-b8a9c0ea5c8b' User entered 'None (0)'	System	02 Sep 2020 01:18:23
	System	02 Sep 2020 01:18:23

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:01', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '75656a39-be9d-44f9-9236-b8a9c0ea5c8b'	System	02 Sep 2020 01:18:23
User entered 'Some interference with activity (2)'	System	02 Sep 2020 01:18:23

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:03:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:04', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '75656a39-be9d-44f9-9236-b8a9c0ea5c8b' User entered 'None (0)'	System	02 Sep 2020 01:18:23
	System	02 Sep 2020 01:18:23



US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:03:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:11', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '75656a39-be9d-44f9-9236-b8a9c0ea5c8b' User entered 'No interference with activity (1)'	System	02 Sep 2020 01:18:23
	System	02 Sep 2020 01:18:23

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:13', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '75656a39-be9d-44f9-9236-b8a9c0ea5c8b' User entered 'None (0)'	System	02 Sep 2020 01:18:23
	System	02 Sep 2020 01:18:23

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:15', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '75656a39-be9d-44f9-9236-b8a9c0ea5c8b' User entered 'None (0)'	System	02 Sep 2020 01:18:23
	System	02 Sep 2020 01:18:23

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:17', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '75656a39-be9d-44f9-9236-b8a9c0ea5c8b' User entered 'No (N)'	System	02 Sep 2020 01:18:23
	System	02 Sep 2020 01:18:23

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-01T18:18:20', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '75656a39-be9d-44f9-9236-b8a9c0ea5c8b' User entered '01 Sep 2020 18:18'	System	02 Sep 2020 01:18:23
	System	02 Sep 2020 01:18:23

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '01 Sep 2020 12:00'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '02 Sep 2020 11:59'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 5'	System	29 Aug 2020 18:33:00



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:31', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '1dee984e-67a0-4ed6-97ee-91efb7c086b6' User entered 'None (0)'	System	03 Sep 2020 12:18:01
	System	03 Sep 2020 12:18:01

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:36', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '1dee984e-67a0-4ed6-97ee-91efb7c086b6'	System	03 Sep 2020 12:18:01
User entered 'Some interference with activity (2)'	System	03 Sep 2020 12:18:01

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:03:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:41', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '1dee984e-67a0-4ed6-97ee-91efb7c086b6' User entered 'None (0)'	System	03 Sep 2020 12:18:01
	System	03 Sep 2020 12:18:01

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:03:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:50', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '1dee984e-67a0-4ed6-97ee-91efb7c086b6' User entered 'None (0)'	System	03 Sep 2020 12:18:01
	System	03 Sep 2020 12:18:01

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:51', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '1dee984e-67a0-4ed6-97ee-91efb7c086b6' User entered 'None (0)'	System	03 Sep 2020 12:18:01
	System	03 Sep 2020 12:18:01

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:53', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '1dee984e-67a0-4ed6-97ee-91efb7c086b6' User entered 'None (0)'	System	03 Sep 2020 12:18:01
	System	03 Sep 2020 12:18:01

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:55', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '1dee984e-67a0-4ed6-97ee-91efb7c086b6' User entered 'No (N)'	System	03 Sep 2020 12:18:01
	System	03 Sep 2020 12:18:01

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T05:17:57', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '1dee984e-67a0-4ed6-97ee-91efb7c086b6' User entered '03 Sep 2020 05:17'	System	03 Sep 2020 12:18:01
	System	03 Sep 2020 12:18:01



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '02 Sep 2020 12:00'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '03 Sep 2020 11:59'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 6'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:59:13', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f68fe507-55e2-4d04-b9b7-90c018d279d8' User entered 'None (0)'	System	04 Sep 2020 03:59:40
	System	04 Sep 2020 03:59:40

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:59:17', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f68fe507-55e2-4d04-b9b7-90c018d279d8'	System	04 Sep 2020 03:59:40
User entered 'No interference with activity (1)'	System	04 Sep 2020 03:59:40

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:03:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:59:25', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f68fe507-55e2-4d04-b9b7-90c018d279d8' User entered 'None (0)'	System	04 Sep 2020 03:59:40
	System	04 Sep 2020 03:59:40

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:03:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:59:27', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f68fe507-55e2-4d04-b9b7-90c018d279d8' User entered 'None (0)'	System	04 Sep 2020 03:59:40
	System	04 Sep 2020 03:59:40

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:59:30', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f68fe507-55e2-4d04-b9b7-90c018d279d8' User entered 'None (0)'	System	04 Sep 2020 03:59:40
	System	04 Sep 2020 03:59:40



**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:59:33', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f68fe507-55e2-4d04-b9b7-90c018d279d8' User entered 'None (0)'	System	04 Sep 2020 03:59:40
	System	04 Sep 2020 03:59:40

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:59:35', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f68fe507-55e2-4d04-b9b7-90c018d279d8' User entered 'No (N)'	System	04 Sep 2020 03:59:40
	System	04 Sep 2020 03:59:40

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-03T20:59:38', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f68fe507-55e2-4d04-b9b7-90c018d279d8' User entered '03 Sep 2020 20:59'	System	04 Sep 2020 03:59:40
	System	04 Sep 2020 03:59:40

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '03 Sep 2020 12:00'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '04 Sep 2020 11:59'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 7'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:35:58', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c75e29bd-6bcf-43f4-ad89-55e11f183360' User entered 'None (0)'	System	05 Sep 2020 04:36:28
	System	05 Sep 2020 04:36:28

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:36:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c75e29bd-6bcf-43f4-ad89-55e11f183360' User entered 'None (0)'	System	05 Sep 2020 04:36:28
	System	05 Sep 2020 04:36:28



US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:03:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:36:08', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c75e29bd-6bcf-43f4-ad89-55e11f183360' User entered 'None (0)'	System	05 Sep 2020 04:36:28
	System	05 Sep 2020 04:36:28

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:36:10', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c75e29bd-6bcf-43f4-ad89-55e11f183360' User entered 'None (0)'	System	05 Sep 2020 04:36:28
	System	05 Sep 2020 04:36:28

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:36:13', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c75e29bd-6bcf-43f4-ad89-55e11f183360' User entered 'None (0)'	System	05 Sep 2020 04:36:28
	System	05 Sep 2020 04:36:28

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:36:17', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c75e29bd-6bcf-43f4-ad89-55e11f183360' User entered 'None (0)'	System	05 Sep 2020 04:36:28
	System	05 Sep 2020 04:36:28

US3192575

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:36:20', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c75e29bd-6bcf-43f4-ad89-55e11f183360' User entered 'No (N)'	System	05 Sep 2020 04:36:28
	System	05 Sep 2020 04:36:28

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-04T21:36:23', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c75e29bd-6bcf-43f4-ad89-55e11f183360' User entered '04 Sep 2020 21:36'	System	05 Sep 2020 04:36:28
	System	05 Sep 2020 04:36:28

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '04 Sep 2020 12:00'	System	29 Aug 2020 18:33:00

**US3192575**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '05 Sep 2020 11:59'	System	29 Aug 2020 18:33:00



**US3192575**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 02:15:27

**US3192575**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered '7 Sep 2020'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 02:15:27

**US3192575**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Contact Made (CONTACT MADE)'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 02:15:27

**US3192575**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered empty.	Yvonne De Los Reyes (b) (4)	16 Sep 2020 02:15:27

**US3192575**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 02:15:32

**US3192575**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered '1'	System	16 Sep 2020 02:15:32

**US3192575**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:02:59
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 02:15:44

**US3192575**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:02:59
User entered '15 Sep 2020'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 02:15:44



**US3192575**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:02:59
User entered 'Contact Made (CONTACT MADE)'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 02:15:44

**US3192575**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:02:59
User entered empty.	Yvonne De Los Reyes (b) (4)	16 Sep 2020 02:15:44

**US3192575**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:02:59
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 02:15:48

**US3192575**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered 'I'	System	16 Sep 2020 02:15:48

**US3192575**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Sep 2020 21:49:43

**US3192575**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered '21 Sep 2020'	Zoe Sesma (b) (4)	21 Sep 2020 21:49:43

**US3192575**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4)	21 Sep 2020 21:49:43

**US3192575**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered empty.	Zoe Sesma (b) (4)	21 Sep 2020 21:49:43



US3192575

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Sep 2020 21:49:47

**US3192575**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered 'I'	System	21 Sep 2020 21:49:47

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Tianna Young (b) (4)	26 Sep 2020 19:09:00

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '26 Sep 2020'	Tianna Young (b) (4)	26 Sep 2020 19:09:00

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Clinic (Clinic)'	Tianna Young (b) (4)	26 Sep 2020 19:09:00

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'VISIT2'	System	26 Sep 2020 19:09:00

US3192575

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User accepted default value 'Pre-Dose (PREDOSE)'	Tianna Young (b) (4)	26 Sep 2020 19:15:57
	(b) (4)	

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Tianna Young (b) (4)	26 Sep 2020 19:15:57



**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '26 Sep 2020'	Tianna Young (b) (4)	26 Sep 2020 19:15:57

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '11:25'	Tianna Young (b) (4)	26 Sep 2020 19:15:57

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered '26 Sep 2020 11:25'	System	26 Sep 2020 19:15:57

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '98.0' F	Tianna Young (b) (4)	26 Sep 2020 19:15:57

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Oral (Oral)'	Tianna Young (b) (4)	26 Sep 2020 19:15:57

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Tianna Young (b) (4)	26 Sep 2020 19:15:57

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '86'	Tianna Young (b) (4)	26 Sep 2020 19:15:57

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'bpm'	System	26 Sep 2020 19:15:57



**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '16'	Tianna Young (b) (4)	26 Sep 2020 19:15:57

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'breaths/min'	System	26 Sep 2020 19:15:57

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '114'	Tianna Young (b) (4)	26 Sep 2020 19:15:57

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'mmHg'	System	26 Sep 2020 19:15:57

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '81'	Tianna Young (b) (4)	26 Sep 2020 19:15:57

US3192575

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:43

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'mmHg'	System	26 Sep 2020 19:15:57

US3192575

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User closed query 'Subject received Day 29 dose. Post dose vitals are expected. Please reconcile. Thanks' (Site from CRA).		15 Jan 2021 20:20:39
Query 'Subject received Day 29 dose. Post dose vitals are expected. Please reconcile. Thanks' answered with 'updated' (Site from CRA).	maggie Tono (b) (4) (b) (4)	31 Dec 2020 17:04:10
User entered 'Post-Dose (POSTDOSE)'	System	31 Dec 2020 17:03:56
User opened query 'Subject received Day 29 dose. Post dose vitals are expected. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	24 Dec 2020 00:07:24

US3192575

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	maggie Tono (b) (4)	31 Dec 2020 17:03:56



US3192575

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '26 Sep 2020'	maggie Tono (b) (4)	31 Dec 2020 17:03:56

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '12:30'	maggie Tono (b) (4)	31 Dec 2020 17:03:56

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered '26 Sep 2020 12:30'	System	31 Dec 2020 17:03:56

US3192575

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '98.3' F	maggie Tono (b) (4)	31 Dec 2020 17:03:56

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Oral (Oral)'	maggie Tono (b) (4)	31 Dec 2020 17:03:56

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	(b) (4) maggie Tono (b) (4)	31 Dec 2020 17:03:56

US3192575

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	31 Dec 2020 17:04:20
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	31 Dec 2020 17:04:20
User entered '61' reason for change: Data Entry Error	maggie Tono (b) (4)	31 Dec 2020 17:04:20
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	31 Dec 2020 17:03:56
User entered '1'	System	31 Dec 2020 17:03:56
	maggie Tono (b) (4)	31 Dec 2020 17:03:56
	(b) (4)	

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'bpm'	System	31 Dec 2020 17:03:56



**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '14'	maggie Tono (b) (4)	31 Dec 2020 17:03:56

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'breaths/min'	System	31 Dec 2020 17:03:56

US3192575

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '117'	maggie Tono (b) (4)	31 Dec 2020 17:03:56

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'mmHg'	System	31 Dec 2020 17:03:56

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '86'	maggie Tono (b) (4)	31 Dec 2020 17:03:56

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'mmHg'	System	31 Dec 2020 17:03:56

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:03:43**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Tianna Young (b) (4)	26 Sep 2020 19:09:25

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:03:43**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '26 Sep 2020'	Tianna Young (b) (4)	26 Sep 2020 19:09:25



**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Tianna Young (b) (4)	26 Sep 2020 19:11:40

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '26 Sep 2020'	Tianna Young (b) (4)	26 Sep 2020 19:11:40

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Urine (URINE)'	Tianna Young (b) (4)	26 Sep 2020 19:11:40

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Negative (NEGATIVE)'	Tianna Young (b) (4)	26 Sep 2020 19:11:40

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Tianna Young (b) (4)	26 Sep 2020 19:11:40

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Tianna Young (b) (4)	26 Sep 2020 19:11:40

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Tianna Young (b) (4)	26 Sep 2020 19:11:40

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered empty.	System	26 Sep 2020 19:11:40



**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Tianna Young (b) (4)	26 Sep 2020 19:09:40

US3192575

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Tianna Young (b) (4)	26 Sep 2020 19:09:40

US3192575

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Tianna Young (b) (4)	26 Sep 2020 19:09:40

US3192575

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'MRNA-1273 OR PLACEBO'	System	26 Sep 2020 19:09:40

US3192575

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '26 Sep 2020'	Tianna Young (b) (4)	26 Sep 2020 19:09:40

US3192575

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '11:59'	Tianna Young (b) (4)	26 Sep 2020 19:09:40

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered '26 Sep 2020 11:59'	System	26 Sep 2020 19:09:40

US3192575

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Left Arm (LEFT ARM)'	Tianna Young (b) (4)	26 Sep 2020 19:09:40



US3192575

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'ONCE'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'INTRAMUSCULAR'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Tianna Young (b) (4)	26 Sep 2020 19:12:20

US3192575

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '26 Sep 2020'	Tianna Young (b) (4)	26 Sep 2020 19:12:20

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '11:45' reason for change: Data Entry Error	(b) (4)	
	Tianna Young (b) (4)	26 Sep 2020 19:16:33
User entered '11:40'	(b) (4)	
	Tianna Young (b) (4)	26 Sep 2020 19:12:20
	(b) (4)	

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered '26 Sep 2020 11:45'	System	26 Sep 2020 19:16:33
User entered '26 Sep 2020 11:40'	System	26 Sep 2020 19:12:20

US3192575

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:03:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '26 Sep 2020'	Tianna Young (b) (4)	26 Sep 2020 19:16:25

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tianna Young (b) (4) (b) (4)	26 Sep 2020 19:16:25



**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Tianna Young (b) (4)	26 Sep 2020 19:16:25

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '11:51'	Tianna Young (b) (4)	26 Sep 2020 19:16:25

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered '26 Sep 2020 11:51'	System	26 Sep 2020 19:16:25

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tianna Young (b) (4) (b) (4)	26 Sep 2020 19:16:25

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'No (N)'	Tianna Young (b) (4)	26 Sep 2020 19:16:25

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Tianna Young (b) (4)	26 Sep 2020 19:16:25

**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered empty.	System	26 Sep 2020 19:16:25

US3192575

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Tianna Young (b) (4)	26 Sep 2020 19:12:55



**US3192575**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered '1'	System	26 Sep 2020 19:12:55

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:05', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'ac6909f6-7c12-47b5-aef9-cdf92dca99d2' User entered 'Yes (Y)'	System	26 Sep 2020 19:22:18
	System	26 Sep 2020 19:22:18

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:08', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'ac6909f6-7c12-47b5-aef9-cdf92dca99d2' User entered '98.3'	System	26 Sep 2020 19:22:18
	System	26 Sep 2020 19:22:18

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:11', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'ac6909f6-7c12-47b5-aef9-cdf92dca99d2'	System	26 Sep 2020 19:22:18
User entered 'No (N)'	System	26 Sep 2020 19:22:18

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:13', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'ac6909f6-7c12-47b5-aef9-cdf92dca99d2'	System	26 Sep 2020 19:22:18
User entered '26 Sep 2020 12:22'	System	26 Sep 2020 19:22:18

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '26 Sep 2020 12:19'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '26 Sep 2020 14:49'	System	26 Sep 2020 19:09:40



US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:09:37', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '413308a4-6c52-4dfb-87e8-c1d2ced11310' User entered 'Yes (Y)'	System	26 Sep 2020 23:10:06
	System	26 Sep 2020 23:10:06

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:09:56', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '413308a4-6c52-4dfb-87e8-c1d2ced11310' User entered '97.7'	System	26 Sep 2020 23:10:06
	System	26 Sep 2020 23:10:06

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:09:59', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '413308a4-6c52-4dfb-87e8-c1d2ced11310' User entered 'No (N)'	System	26 Sep 2020 23:10:06
	System	26 Sep 2020 23:10:06

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:10:01', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '413308a4-6c52-4dfb-87e8-c1d2ced11310' User entered '26 Sep 2020 16:10'	System	26 Sep 2020 23:10:06
	System	26 Sep 2020 23:10:06

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '26 Sep 2020 15:44'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 2'	System	26 Sep 2020 19:09:40



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:48:31', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12be31ca-a620-4409-83ef-801a591f53fb' User entered 'Yes (Y)'	System	28 Sep 2020 00:48:45
	System	28 Sep 2020 00:48:45

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:48:35', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12be31ca-a620-4409-83ef-801a591f53fb' User entered '96.7'	System	28 Sep 2020 00:48:45
	System	28 Sep 2020 00:48:45

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:48:38', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12be31ca-a620-4409-83ef-801a591f53fb' User entered 'No (N)'	System	28 Sep 2020 00:48:45
	System	28 Sep 2020 00:48:45

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:48:40', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '12be31ca-a620-4409-83ef-801a591f53fb' User entered '27 Sep 2020 17:48'	System	28 Sep 2020 00:48:45
	System	28 Sep 2020 00:48:45

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 3'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:05:29', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17968553-b517-4aec-970d-7ff460303e56' User entered 'Yes (Y)'	System	29 Sep 2020 12:05:47
	System	29 Sep 2020 12:05:47



US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:05:34', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17968553-b517-4aec-970d-7ff460303e56' User entered '97.1'	System	29 Sep 2020 12:05:47
	System	29 Sep 2020 12:05:47

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:05:38', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17968553-b517-4aec-970d-7ff460303e56'	System	29 Sep 2020 12:05:47
User entered 'Yes (Y)'	System	29 Sep 2020 12:05:47

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
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 'ibuprofen 200mgs for soreness in the injection site' (Site from System).	(b) (4)	01 Oct 2020 18:12:38
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).	maggie Tono (b) (4)	01 Oct 2020 01:03:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:05:41', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17968553-b517-4aec-970d-7ff460303e56'	System	29 Sep 2020 12:05:47
User entered '1'	System	29 Sep 2020 12:05:47

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Aug 2021 22:03:43

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:05:41', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17968553-b517-4aec-970d-7ff460303e56' User entered '0'	System	29 Sep 2020 12:05:47
	System	29 Sep 2020 12:05:47

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:05:44', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '17968553-b517-4aec-970d-7ff460303e56' User entered '29 Sep 2020 05:05'	System	29 Sep 2020 12:05:47
	System	29 Sep 2020 12:05:47

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 4'	System	26 Sep 2020 19:09:40



US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:03:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:24:17', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd9692f99-a007-4379-884e-94df0c54bd3a' User entered 'Yes (Y)'	System	30 Sep 2020 02:24:32
	System	30 Sep 2020 02:24:32

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:24:21', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd9692f99-a007-4379-884e-94df0c54bd3a' User entered '96.4'	System	30 Sep 2020 02:24:32
	System	30 Sep 2020 02:24:32

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:24:27', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd9692f99-a007-4379-884e-94df0c54bd3a' User entered 'No (N)'	System	30 Sep 2020 02:24:32
	System	30 Sep 2020 02:24:32

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:24:29', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd9692f99-a007-4379-884e-94df0c54bd3a' User entered '29 Sep 2020 19:24'	System	30 Sep 2020 02:24:32
	System	30 Sep 2020 02:24:32

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 5'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:03:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T20:59:46', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '0851a652-341a-4241-bdd4-7ec1938b9e3d' User entered 'Yes (Y)'	System	01 Oct 2020 04:00:03
	System	01 Oct 2020 04:00:03



US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T20:59:51', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '0851a652-341a-4241-bdd4-7ec1938b9e3d' User entered '97.5'	System	01 Oct 2020 04:00:03
	System	01 Oct 2020 04:00:03

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T20:59:53', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '0851a652-341a-4241-bdd4-7ec1938b9e3d' User entered 'No (N)'	System	01 Oct 2020 04:00:03
	System	01 Oct 2020 04:00:03

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T20:59:55', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '0851a652-341a-4241-bdd4-7ec1938b9e3d' User entered '30 Sep 2020 20:59'	System	01 Oct 2020 04:00:03
	System	01 Oct 2020 04:00:03

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 6'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:03:43

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T05:59:22', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'cc6f5c12-f04e-4467-bdf6-f981664f3e8c' User entered 'Yes (Y)'	System	02 Oct 2020 12:59:38
	System	02 Oct 2020 12:59:38

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T05:59:27', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'cc6f5c12-f04e-4467-bdf6-f981664f3e8c' User entered '97.3'	System	02 Oct 2020 12:59:38
	System	02 Oct 2020 12:59:38



US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T05:59:30', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'cc6f5c12-f04e-4467-bdf6-f981664f3e8c' User entered 'No (N)'	System	02 Oct 2020 12:59:38
	System	02 Oct 2020 12:59:38

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T05:59:32', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'cc6f5c12-f04e-4467-bdf6-f981664f3e8c' User entered '02 Oct 2020 05:59'	System	02 Oct 2020 12:59:38
	System	02 Oct 2020 12:59:38

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 7'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:50:33', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3bf8fd6c-4c70-4eb8-a4b6-a46b17661c57' User entered 'Yes (Y)'	System	03 Oct 2020 04:51:18
	System	03 Oct 2020 04:51:18

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:03:43

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:50:53', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3bf8fd6c-4c70-4eb8-a4b6-a46b17661c57' User entered '97.4'	System	03 Oct 2020 04:51:18
	System	03 Oct 2020 04:51:18

US3192575

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:51:05', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3bf8fd6c-4c70-4eb8-a4b6-a46b17661c57'	System	03 Oct 2020 04:51:18
User entered 'No (N)'	System	03 Oct 2020 04:51:18



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:51:15', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3bf8fd6c-4c70-4eb8-a4b6-a46b17661c57' User entered '02 Oct 2020 21:51'	System	03 Oct 2020 04:51:18
	System	03 Oct 2020 04:51:18

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:19', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '355d9fe9-faf4-444a-a092-88e15dfbc2a5' User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 19:22:37
	System	26 Sep 2020 19:22:37

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:23', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '355d9fe9-faf4-444a-a092-88e15dfbc2a5' User entered 'No (N)'	System	26 Sep 2020 19:22:37
	System	26 Sep 2020 19:22:37

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:28', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '355d9fe9-faf4-444a-a092-88e15dfbc2a5' User entered 'No (N)'	System	26 Sep 2020 19:22:37
	System	26 Sep 2020 19:22:37

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:31', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '355d9fe9-faf4-444a-a092-88e15dfbc2a5'	System	26 Sep 2020 19:22:37
User entered 'None (1)'	System	26 Sep 2020 19:22:37



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:33', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '355d9fe9-faf4-444a-a092-88e15dfbc2a5' User entered '26 Sep 2020 12:22'	System	26 Sep 2020 19:22:37
	System	26 Sep 2020 19:22:37

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '26 Sep 2020 12:19'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '26 Sep 2020 14:49'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:10:13', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '265a72ce-e9ba-444e-ab7b-affa60fde6cf' User entered 'None (1)'	System	26 Sep 2020 23:10:29
	System	26 Sep 2020 23:10:29

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:10:18', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '265a72ce-e9ba-444e-ab7b-affa60fde6cf' User entered 'No (N)'	System	26 Sep 2020 23:10:29
	System	26 Sep 2020 23:10:29

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:10:21', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '265a72ce-e9ba-444e-ab7b-affa60fde6cf' User entered 'No (N)'	System	26 Sep 2020 23:10:29
	System	26 Sep 2020 23:10:29

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:10:25', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '265a72ce-e9ba-444e-ab7b-affa60fde6cf' User entered 'None (1)'	System	26 Sep 2020 23:10:29
	System	26 Sep 2020 23:10:29



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:10:27', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '265a72ce-e9ba-444e-ab7b-affa60fde6cf' User entered '26 Sep 2020 16:10'	System	26 Sep 2020 23:10:29
	System	26 Sep 2020 23:10:29

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '26 Sep 2020 15:44'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 2'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:48:48', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c8cd8d63-dba6-4716-990c-7b78a2da549f'	System	28 Sep 2020 00:49:10
User entered 'Does not interfere with activity (2)'	System	28 Sep 2020 00:49:10

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:03:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:48:52', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c8cd8d63-dba6-4716-990c-7b78a2da549f' User entered 'No (N)'	System	28 Sep 2020 00:49:10
	System	28 Sep 2020 00:49:10

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:49:01', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c8cd8d63-dba6-4716-990c-7b78a2da549f' User entered 'No (N)'	System	28 Sep 2020 00:49:10
	System	28 Sep 2020 00:49:10

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:49:04', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c8cd8d63-dba6-4716-990c-7b78a2da549f' User entered 'None (1)'	System	28 Sep 2020 00:49:10
	System	28 Sep 2020 00:49:10



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:49:07', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c8cd8d63-dba6-4716-990c-7b78a2da549f' User entered '27 Sep 2020 17:49'	System	28 Sep 2020 00:49:10
	System	28 Sep 2020 00:49:10

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 3'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:05:50', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f84bfa02-b0d2-4897-afba-87fab01d2e50'	System	29 Sep 2020 12:06:02
User entered 'None (1)'	System	29 Sep 2020 12:06:02

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:05:53', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f84bfa02-b0d2-4897-afba-87fab01d2e50'	System	29 Sep 2020 12:06:02
User entered 'No (N)'	System	29 Sep 2020 12:06:02

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:05:55', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f84bfa02-b0d2-4897-afba-87fab01d2e50' User entered 'No (N)'	System	29 Sep 2020 12:06:02
	System	29 Sep 2020 12:06:02

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:05:57', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f84bfa02-b0d2-4897-afba-87fab01d2e50' User entered 'None (1)'	System	29 Sep 2020 12:06:02
	System	29 Sep 2020 12:06:02



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:05:59', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f84bfa02-b0d2-4897-afba-87fab01d2e50' User entered '29 Sep 2020 05:05'	System	29 Sep 2020 12:06:02
	System	29 Sep 2020 12:06:02

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 4'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:24:36', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7233c820-0cd0-4ddb-b842-c17e25278169'	System	30 Sep 2020 02:25:04
User entered 'None (1)'	System	30 Sep 2020 02:25:04

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:03:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:24:44', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7233c820-0cd0-4ddb-b842-c17e25278169' User entered 'No (N)'	System	30 Sep 2020 02:25:04
	System	30 Sep 2020 02:25:04

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:24:54', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7233c820-0cd0-4ddb-b842-c17e25278169' User entered 'No (N)'	System	30 Sep 2020 02:25:04
	System	30 Sep 2020 02:25:04

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:24:58', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7233c820-0cd0-4ddb-b842-c17e25278169'	System	30 Sep 2020 02:25:04
User entered 'None (1)'	System	30 Sep 2020 02:25:04



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:25:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7233c820-0cd0-4ddb-b842-c17e25278169' User entered '29 Sep 2020 19:25'	System	30 Sep 2020 02:25:04
	System	30 Sep 2020 02:25:04

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 5'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T21:00:01', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'b2944f8e-3160-41b7-b844-8be1ab610de3' User entered 'None (1)'	System	01 Oct 2020 04:00:20
	System	01 Oct 2020 04:00:20

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:03:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T21:00:03', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'b2944f8e-3160-41b7-b844-8be1ab610de3' User entered 'No (N)'	System	01 Oct 2020 04:00:20
	System	01 Oct 2020 04:00:20

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T21:00:06', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'b2944f8e-3160-41b7-b844-8be1ab610de3' User entered 'No (N)'	System	01 Oct 2020 04:00:20
	System	01 Oct 2020 04:00:20

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T21:00:10', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'b2944f8e-3160-41b7-b844-8be1ab610de3' User entered 'None (1)'	System	01 Oct 2020 04:00:20
	System	01 Oct 2020 04:00:20



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T21:00:16', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'b2944f8e-3160-41b7-b844-8be1ab610de3' User entered '30 Sep 2020 21:00'	System	01 Oct 2020 04:00:20
	System	01 Oct 2020 04:00:20

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 6'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T05:59:37', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '2140a3de-3085-4bdd-9c02-09bcd93972a1' User entered 'None (1)'	System	02 Oct 2020 12:59:51
	System	02 Oct 2020 12:59:51

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:03:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T05:59:41', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '2140a3de-3085-4bdd-9c02-09bcd93972a1' User entered 'No (N)'	System	02 Oct 2020 12:59:51
	System	02 Oct 2020 12:59:51

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T05:59:44', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '2140a3de-3085-4bdd-9c02-09bcd93972a1' User entered 'No (N)'	System	02 Oct 2020 12:59:51
	System	02 Oct 2020 12:59:51

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T05:59:47', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '2140a3de-3085-4bdd-9c02-09bcd93972a1' User entered 'None (1)'	System	02 Oct 2020 12:59:51
	System	02 Oct 2020 12:59:51



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T05:59:49', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '2140a3de-3085-4bdd-9c02-09bcd93972a1' User entered '02 Oct 2020 05:59'	System	02 Oct 2020 12:59:51
	System	02 Oct 2020 12:59:51

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 7'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:51:23', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'b8c354b1-188b-430c-9811-459e1596f859'	System	03 Oct 2020 04:51:46
User entered 'None (1)'	System	03 Oct 2020 04:51:46

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:03:43

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:51:26', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'b8c354b1-188b-430c-9811-459e1596f859' User entered 'No (N)'	System	03 Oct 2020 04:51:46
	System	03 Oct 2020 04:51:46

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:51:30', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'b8c354b1-188b-430c-9811-459e1596f859' User entered 'No (N)'	System	03 Oct 2020 04:51:46
	System	03 Oct 2020 04:51:46

US3192575

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Aug 2021 22:03:43

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:51:40', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'b8c354b1-188b-430c-9811-459e1596f859' User entered 'None (1)'	System	03 Oct 2020 04:51:46
	System	03 Oct 2020 04:51:46



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:51:43', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'b8c354b1-188b-430c-9811-459e1596f859' User entered '02 Oct 2020 21:51'	System	03 Oct 2020 04:51:46
	System	03 Oct 2020 04:51:46

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:37', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f077501c-ea3c-43a0-922e-cbc448169fa1' User entered 'None (0)'	System	26 Sep 2020 19:22:54
	System	26 Sep 2020 19:22:54

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:39', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f077501c-ea3c-43a0-922e-cbc448169fa1' User entered 'None (0)'	System	26 Sep 2020 19:22:54
	System	26 Sep 2020 19:22:54

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:41', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f077501c-ea3c-43a0-922e-cbc448169fa1' User entered 'None (0)'	System	26 Sep 2020 19:22:54
	System	26 Sep 2020 19:22:54

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:43', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f077501c-ea3c-43a0-922e-cbc448169fa1' User entered 'None (0)'	System	26 Sep 2020 19:22:54
	System	26 Sep 2020 19:22:54



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:45', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f077501c-ea3c-43a0-922e-cbc448169fa1' User entered 'None (0)'	System	26 Sep 2020 19:22:54
	System	26 Sep 2020 19:22:54

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:46', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f077501c-ea3c-43a0-922e-cbc448169fa1' User entered 'None (0)'	System	26 Sep 2020 19:22:54
	System	26 Sep 2020 19:22:54

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:49', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f077501c-ea3c-43a0-922e-cbc448169fa1' User entered 'No (N)'	System	26 Sep 2020 19:22:54
	System	26 Sep 2020 19:22:54

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T12:22:51', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f077501c-ea3c-43a0-922e-cbc448169fa1' User entered '26 Sep 2020 12:22'	System	26 Sep 2020 19:22:54
	System	26 Sep 2020 19:22:54

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '26 Sep 2020 12:19'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '26 Sep 2020 14:49'	System	26 Sep 2020 19:09:40

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 1, after vaccination (at home)'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:10:30', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'a51240c8-6f3b-469d-b45c-16a2010fd2f7' User entered 'None (0)'	System	26 Sep 2020 23:10:45
	System	26 Sep 2020 23:10:45



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:10:32', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'a51240c8-6f3b-469d-b45c-16a2010fd2f7' User entered 'None (0)'	System	26 Sep 2020 23:10:45
	System	26 Sep 2020 23:10:45

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:10:34', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'a51240c8-6f3b-469d-b45c-16a2010fd2f7' User entered 'None (0)'	System	26 Sep 2020 23:10:45
	System	26 Sep 2020 23:10:45

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:10:36', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'a51240c8-6f3b-469d-b45c-16a2010fd2f7' User entered 'None (0)'	System	26 Sep 2020 23:10:45
	System	26 Sep 2020 23:10:45

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:10:37', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'a51240c8-6f3b-469d-b45c-16a2010fd2f7' User entered 'None (0)'	System	26 Sep 2020 23:10:45
	System	26 Sep 2020 23:10:45

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:10:39', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'a51240c8-6f3b-469d-b45c-16a2010fd2f7' User entered 'None (0)'	System	26 Sep 2020 23:10:45
	System	26 Sep 2020 23:10:45

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:10:41', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'a51240c8-6f3b-469d-b45c-16a2010fd2f7' User entered 'No (N)'	System	26 Sep 2020 23:10:45
	System	26 Sep 2020 23:10:45

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-26T16:10:43', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'a51240c8-6f3b-469d-b45c-16a2010fd2f7'	System	26 Sep 2020 23:10:45
User entered '26 Sep 2020 16:10'	System	26 Sep 2020 23:10:45

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '26 Sep 2020 15:44'	System	26 Sep 2020 19:09:40



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '27 Sep 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 2'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:49:12', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3e4949a7-425b-46e7-b484-4b1035aa32b5'	System	28 Sep 2020 00:49:44
User entered 'No interference with activity (1)'	System	28 Sep 2020 00:49:44

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:49:18', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3e4949a7-425b-46e7-b484-4b1035aa32b5'	System	28 Sep 2020 00:49:44
User entered 'Some interference with activity (2)'	System	28 Sep 2020 00:49:44

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:03:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:49:24', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3e4949a7-425b-46e7-b484-4b1035aa32b5' User entered 'None (0)'	System	28 Sep 2020 00:49:44
	System	28 Sep 2020 00:49:44

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:49:29', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3e4949a7-425b-46e7-b484-4b1035aa32b5' User entered 'None (0)'	System	28 Sep 2020 00:49:44
	System	28 Sep 2020 00:49:44

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:49:31', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3e4949a7-425b-46e7-b484-4b1035aa32b5' User entered 'None (0)'	System	28 Sep 2020 00:49:44
	System	28 Sep 2020 00:49:44

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:49:33', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3e4949a7-425b-46e7-b484-4b1035aa32b5' User entered 'None (0)'	System	28 Sep 2020 00:49:44
	System	28 Sep 2020 00:49:44



US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:49:35', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3e4949a7-425b-46e7-b484-4b1035aa32b5' User entered 'No (N)'	System	28 Sep 2020 00:49:44
	System	28 Sep 2020 00:49:44

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-27T17:49:39', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3e4949a7-425b-46e7-b484-4b1035aa32b5' User entered '27 Sep 2020 17:49'	System	28 Sep 2020 00:49:44
	System	28 Sep 2020 00:49:44

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '27 Sep 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '28 Sep 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 3'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:06:05', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7aae440f-b60b-4cca-ba42-ecc1345c1dd5' User entered 'None (0)'	System	29 Sep 2020 12:06:35
	System	29 Sep 2020 12:06:35

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:06:09', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7aae440f-b60b-4cca-ba42-ecc1345c1dd5'	System	29 Sep 2020 12:06:35
User entered 'No interference with activity (1)'	System	29 Sep 2020 12:06:35

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:06:15', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7aae440f-b60b-4cca-ba42-ecc1345c1dd5'	System	29 Sep 2020 12:06:35
User entered 'No interference with activity (1)'	System	29 Sep 2020 12:06:35



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:06:21', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7aae440f-b60b-4cca-ba42-ecc1345c1dd5'	System	29 Sep 2020 12:06:35
User entered 'No interference with activity (1)'	System	29 Sep 2020 12:06:35

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:06:23', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7aae440f-b60b-4cca-ba42-ecc1345c1dd5' User entered 'None (0)'	System	29 Sep 2020 12:06:35
	System	29 Sep 2020 12:06:35

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:06:25', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7aae440f-b60b-4cca-ba42-ecc1345c1dd5' User entered 'None (0)'	System	29 Sep 2020 12:06:35
	System	29 Sep 2020 12:06:35

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:06:28', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7aae440f-b60b-4cca-ba42-ecc1345c1dd5' User entered 'No (N)'	System	29 Sep 2020 12:06:35
	System	29 Sep 2020 12:06:35

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T05:06:30', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7aae440f-b60b-4cca-ba42-ecc1345c1dd5' User entered '29 Sep 2020 05:06'	System	29 Sep 2020 12:06:35
	System	29 Sep 2020 12:06:35

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '28 Sep 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Sep 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 4'	System	26 Sep 2020 19:09:40



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:25:14', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '18cc486f-1b4f-418c-a149-c1b7d27d529b'	System	30 Sep 2020 02:25:43
User entered 'No interference with activity (1)'	System	30 Sep 2020 02:25:43

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:25:16', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '18cc486f-1b4f-418c-a149-c1b7d27d529b'	System	30 Sep 2020 02:25:43
User entered 'No interference with activity (1)'	System	30 Sep 2020 02:25:43

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:03:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:25:21', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '18cc486f-1b4f-418c-a149-c1b7d27d529b'	System	30 Sep 2020 02:25:43
User entered 'No interference with activity (1)'	System	30 Sep 2020 02:25:43

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:25:24', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '18cc486f-1b4f-418c-a149-c1b7d27d529b' User entered 'None (0)'	System	30 Sep 2020 02:25:43
	System	30 Sep 2020 02:25:43

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:25:27', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '18cc486f-1b4f-418c-a149-c1b7d27d529b' User entered 'None (0)'	System	30 Sep 2020 02:25:43
	System	30 Sep 2020 02:25:43

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:25:29', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '18cc486f-1b4f-418c-a149-c1b7d27d529b' User entered 'None (0)'	System	30 Sep 2020 02:25:43
	System	30 Sep 2020 02:25:43

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:25:32', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '18cc486f-1b4f-418c-a149-c1b7d27d529b' User entered 'No (N)'	System	30 Sep 2020 02:25:43
	System	30 Sep 2020 02:25:43

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-29T19:25:42', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '18cc486f-1b4f-418c-a149-c1b7d27d529b' User entered '29 Sep 2020 19:25'	System	30 Sep 2020 02:25:43
	System	30 Sep 2020 02:25:43



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '29 Sep 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '30 Sep 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 5'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T21:00:20', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3f1bfe47-f316-4ae6-abcd-583f73e5ed0d' User entered 'None (0)'	System	01 Oct 2020 04:00:40
	System	01 Oct 2020 04:00:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T21:00:23', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3f1bfe47-f316-4ae6-abcd-583f73e5ed0d' User entered 'No interference with activity (1)'	System	01 Oct 2020 04:00:40
	System	01 Oct 2020 04:00:40

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:03:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T21:00:26', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3f1bfe47-f316-4ae6-abcd-583f73e5ed0d' User entered 'None (0)'	System	01 Oct 2020 04:00:40
	System	01 Oct 2020 04:00:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T21:00:29', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3f1bfe47-f316-4ae6-abcd-583f73e5ed0d' User entered 'None (0)'	System	01 Oct 2020 04:00:40
	System	01 Oct 2020 04:00:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T21:00:30', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3f1bfe47-f316-4ae6-abcd-583f73e5ed0d' User entered 'None (0)'	System	01 Oct 2020 04:00:40
	System	01 Oct 2020 04:00:40



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T21:00:32', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3f1bfe47-f316-4ae6-abcd-583f73e5ed0d' User entered 'None (0)'	System	01 Oct 2020 04:00:40
	System	01 Oct 2020 04:00:40

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T21:00:34', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3f1bfe47-f316-4ae6-abcd-583f73e5ed0d' User entered 'No (N)'	System	01 Oct 2020 04:00:40
	System	01 Oct 2020 04:00:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-09-30T21:00:36', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3f1bfe47-f316-4ae6-abcd-583f73e5ed0d' User entered '30 Sep 2020 21:00'	System	01 Oct 2020 04:00:40
	System	01 Oct 2020 04:00:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '30 Sep 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '01 Oct 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 6'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T05:59:55', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '71de01e5-822b-4c41-b91e-924fddd02472' User entered 'None (0)'	System	02 Oct 2020 13:00:18
	System	02 Oct 2020 13:00:18

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T05:59:58', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '71de01e5-822b-4c41-b91e-924fddd02472'	System	02 Oct 2020 13:00:18
User entered 'No interference with activity (1)'	System	02 Oct 2020 13:00:18



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T06:00:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '71de01e5-822b-4c41-b91e-924fddd02472' User entered 'None (0)'	System	02 Oct 2020 13:00:18
	System	02 Oct 2020 13:00:18

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T06:00:04', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '71de01e5-822b-4c41-b91e-924fddd02472' User entered 'None (0)'	System	02 Oct 2020 13:00:18
	System	02 Oct 2020 13:00:18

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T06:00:06', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '71de01e5-822b-4c41-b91e-924fddd02472' User entered 'None (0)'	System	02 Oct 2020 13:00:18
	System	02 Oct 2020 13:00:18

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T06:00:09', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '71de01e5-822b-4c41-b91e-924fddd02472' User entered 'None (0)'	System	02 Oct 2020 13:00:18
	System	02 Oct 2020 13:00:18

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T06:00:14', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '71de01e5-822b-4c41-b91e-924fddd02472' User entered 'No (N)'	System	02 Oct 2020 13:00:18
	System	02 Oct 2020 13:00:18

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T06:00:16', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '71de01e5-822b-4c41-b91e-924fddd02472' User entered '02 Oct 2020 06:00'	System	02 Oct 2020 13:00:18
	System	02 Oct 2020 13:00:18

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '01 Oct 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '02 Oct 2020 11:59'	System	26 Sep 2020 19:09:40



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	26 Sep 2020 19:09:40
User entered 'Day 7'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:51:58', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd387a899-804c-4bd7-af0a-081260432e27' User entered 'None (0)'	System	03 Oct 2020 04:52:43
	System	03 Oct 2020 04:52:43

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:52:10', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd387a899-804c-4bd7-af0a-081260432e27'	System	03 Oct 2020 04:52:43
User entered 'No interference with activity (1)'	System	03 Oct 2020 04:52:43

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:03:43

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:52:20', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd387a899-804c-4bd7-af0a-081260432e27' User entered 'None (0)'	System	03 Oct 2020 04:52:43
	System	03 Oct 2020 04:52:43

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:03:43

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:52:23', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd387a899-804c-4bd7-af0a-081260432e27' User entered 'None (0)'	System	03 Oct 2020 04:52:43
	System	03 Oct 2020 04:52:43

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:52:26', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd387a899-804c-4bd7-af0a-081260432e27' User entered 'None (0)'	System	03 Oct 2020 04:52:43
	System	03 Oct 2020 04:52:43

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:52:29', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd387a899-804c-4bd7-af0a-081260432e27' User entered 'None (0)'	System	03 Oct 2020 04:52:43
	System	03 Oct 2020 04:52:43

US3192575

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:52:38', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd387a899-804c-4bd7-af0a-081260432e27' User entered 'No (N)'	System	03 Oct 2020 04:52:43
	System	03 Oct 2020 04:52:43



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-02T21:52:40', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'd387a899-804c-4bd7-af0a-081260432e27' User entered '02 Oct 2020 21:52'	System	03 Oct 2020 04:52:43
	System	03 Oct 2020 04:52:43

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '02 Oct 2020 12:00'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '03 Oct 2020 11:59'	System	26 Sep 2020 19:09:40

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	02 Oct 2020 13:00:18
User entered 'Day 8'	System	02 Oct 2020 13:00:18

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:03:43**

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-03T16:55:31', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'dac95b0c-6834-4d93-92c9-735fc0e5dc3a' User entered 'None (0)'	System	03 Oct 2020 23:55:39
	System	03 Oct 2020 23:55:39

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-03T16:55:36', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'dac95b0c-6834-4d93-92c9-735fc0e5dc3a' User entered '03 Oct 2020 16:55'	System	03 Oct 2020 23:55:39
	System	03 Oct 2020 23:55:39

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 13:00:18

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Fatigue\_Day(8)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 13:00:18



**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	02 Oct 2020 13:00:18
User entered 'Day 8'	System	02 Oct 2020 13:00:18

US3192575

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-03T16:55:40', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'cb46fba5-ea5b-4cae-9fe1-e2f160aae182' User entered 'No (N)'	System	03 Oct 2020 23:55:47
	System	03 Oct 2020 23:55:47

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-03T16:55:42', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'cb46fba5-ea5b-4cae-9fe1-e2f160aae182' User entered '03 Oct 2020 16:55'	System	03 Oct 2020 23:55:47
	System	03 Oct 2020 23:55:47

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 13:00:18

**US3192575**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Aug 2021 22:03:43**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 13:00:18

**US3192575**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	09 Oct 2020 20:33:21

**US3192575**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered '03 Oct 2020'	Norma Barrientos (b) (4)	09 Oct 2020 20:33:21

**US3192575**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Norma Barrientos (b) (4)	09 Oct 2020 20:33:21



**US3192575**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered empty.	Norma Barrientos (b) (4)	09 Oct 2020 20:33:21

US3192575

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	09 Oct 2020 20:33:39

**US3192575**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered 'I'	System	09 Oct 2020 20:33:39

**US3192575**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:38:43

**US3192575**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:38:43

**US3192575**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:38:43

**US3192575**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:38:43

**US3192575**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 21:38:48



**US3192575**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered 'I'	System	13 Oct 2020 21:38:48

**US3192575**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:35:18

**US3192575**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:35:18

**US3192575**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:35:18

**US3192575**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:35:18

**US3192575**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 20:35:23

**US3192575**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered 'I'	System	21 Oct 2020 20:35:23

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:27:19



**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '22 Oct 2020'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:27:19

US3192575

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	System	22 Oct 2020 20:27:38
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	Cynthia Montgomery	22 Oct 2020 20:27:38
User entered empty.	(b) (4)	
	System	22 Oct 2020 20:27:19
	Cynthia Montgomery	22 Oct 2020 20:27:19
	(b) (4)	

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'VISIT3'	System	22 Oct 2020 20:27:19

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:28:11

US3192575

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	22 Oct 2020 20:28:44
User entered '22 Oct 2020' reason for change: Data Entry Error	Cynthia Montgomery (b) (4)	22 Oct 2020 20:28:44
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 20:28:11
User entered empty.	Cynthia Montgomery (b) (4)	22 Oct 2020 20:28:11

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '11:46'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:28:11

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered '22 Oct 2020 11:46'	System	22 Oct 2020 20:28:44
User entered empty.	System	22 Oct 2020 20:28:11

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '97.9' F	Cynthia Montgomery (b) (4)	22 Oct 2020 20:28:11



US3192575

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:43

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Oct 2020 20:28:44
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	22 Oct 2020 20:28:44
User entered 'Oral (Oral)' reason for change: Data Entry Error	Cynthia Montgomery (b) (4)	22 Oct 2020 20:28:44
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 20:28:11
User entered empty.	Cynthia Montgomery (b) (4)	22 Oct 2020 20:28:11

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered empty.	Cynthia Montgomery (b) (4)	22 Oct 2020 20:28:11

US3192575

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:43

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Oct 2020 20:28:44
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Oct 2020 20:28:44
User entered '53' reason for change: Data Entry Error	Cynthia Montgomery	22 Oct 2020 20:28:44
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Oct 2020 20:28:11
User entered empty.	System	22 Oct 2020 20:28:11
	Cynthia Montgomery	22 Oct 2020 20:28:11
	(b) (4)	

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'bpm'	System	22 Oct 2020 20:28:44
User entered empty.	System	22 Oct 2020 20:28:11

US3192575

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:43

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Oct 2020 20:28:44
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Oct 2020 20:28:44
User entered '14' reason for change: Data Entry Error	Cynthia Montgomery	22 Oct 2020 20:28:44
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Oct 2020 20:28:11
User entered empty.	System	22 Oct 2020 20:28:11
	Cynthia Montgomery	22 Oct 2020 20:28:11
	(b) (4)	

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'breaths/min'	System	22 Oct 2020 20:28:44
User entered empty.	System	22 Oct 2020 20:28:11

US3192575

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Oct 2020 20:28:44
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Oct 2020 20:28:44
User entered '120' reason for change: Data Entry Error	Cynthia Montgomery	22 Oct 2020 20:28:44
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Oct 2020 20:28:11
User entered empty.	System	22 Oct 2020 20:28:11
	Cynthia Montgomery	22 Oct 2020 20:28:11
	(b) (4)	

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'mmHg'	System	22 Oct 2020 20:28:44
User entered empty.	System	22 Oct 2020 20:28:11



US3192575

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:43

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Oct 2020 20:28:44
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	22 Oct 2020 20:28:44
User entered '76' reason for change: Data Entry Error	Cynthia Montgomery	22 Oct 2020 20:28:44
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	22 Oct 2020 20:28:11
User entered empty.	System	22 Oct 2020 20:28:11
	Cynthia Montgomery	22 Oct 2020 20:28:11
	(b) (4)	

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered 'mmHg'	System	22 Oct 2020 20:28:44
User entered empty.	System	22 Oct 2020 20:28:11

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:03:43**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:29:00

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:03:43**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '22 Oct 2020'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:29:00

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:29:19

US3192575

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '22 Oct 2020'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:29:19



**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered '12:00'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:29:19

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered '22 Oct 2020 12:00'	System	22 Oct 2020 20:29:19

US3192575

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:10:35
User entered 'Yes (Y)'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:29:33

**US3192575**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:12:01
User entered '1'	System	22 Oct 2020 20:29:33

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 64'	System	29 Aug 2020 18:33:00

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-29T13:06:11', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'ca1d7429-2295-4efc-803e-03eeae42772'	System	29 Oct 2020 20:06:21
User entered 'No (N)'	System	29 Oct 2020 20:06:21

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-29T13:06:14', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'ca1d7429-2295-4efc-803e-03eeae42772'	System	29 Oct 2020 20:06:21
User entered 'No (N)'	System	29 Oct 2020 20:06:21

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-10-29T13:06:17', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'ca1d7429-2295-4efc-803e-03eeae42772' User entered '29 Oct 2020 13:06:17'	System	29 Oct 2020 20:06:21
	System	29 Oct 2020 20:06:21



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered '29 Oct 2020 00:01'	System	29 Aug 2020 18:33:00

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered '02 Nov 2020 23:59'	System	29 Aug 2020 18:33:00

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 71'	System	29 Aug 2020 18:33:00

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-11-06T11:31:56', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '70f04879-7b44-443e-a7a2-b8bf4ccb9f8b' User entered 'No (N)'	System	06 Nov 2020 18:32:04
	System	06 Nov 2020 18:32:04

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-11-06T11:31:58', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '70f04879-7b44-443e-a7a2-b8bf4ccb9f8b' User entered 'No (N)'	System	06 Nov 2020 18:32:04
	System	06 Nov 2020 18:32:04

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-11-06T11:32:01', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '70f04879-7b44-443e-a7a2-b8bf4ccb9f8b' User entered '06 Nov 2020 11:32:01'	System	06 Nov 2020 18:32:04
	System	06 Nov 2020 18:32:04

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered '05 Nov 2020 00:01'	System	29 Aug 2020 18:33:00

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered '09 Nov 2020 23:59'	System	29 Aug 2020 18:33:00



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered 'Day 78'	System	29 Aug 2020 18:33:00

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-11-12T17:12:49', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'ebf2a743-71a2-430f-b5a6-88fb103fbb17'	System	13 Nov 2020 00:13:00
User entered 'No (N)'	System	13 Nov 2020 00:13:00

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-11-12T17:12:52', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'ebf2a743-71a2-430f-b5a6-88fb103fbb17'	System	13 Nov 2020 00:13:00
User entered 'No (N)'	System	13 Nov 2020 00:13:00

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-11-12T17:12:55', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'ebf2a743-71a2-430f-b5a6-88fb103fbb17' User entered '12 Nov 2020 17:12:55'	System	13 Nov 2020 00:13:00
	System	13 Nov 2020 00:13:00

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered '12 Nov 2020 00:01'	System	29 Aug 2020 18:33:00

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:21:05
Data entry locked.	System	29 Aug 2020 18:33:00
User entered '16 Nov 2020 23:59'	System	29 Aug 2020 18:33:00

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-11-19T16:39:56', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f64fc29e-278b-4786-aafa-e5697f53e19b' User entered 'No (N)'	System	19 Nov 2020 23:40:08
	System	19 Nov 2020 23:40:08



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-11-19T16:40:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f64fc29e-278b-4786-aafa-e5697f53e19b' User entered 'No (N)'	System	19 Nov 2020 23:40:08
	System	19 Nov 2020 23:40:08

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-11-19T16:40:04', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f64fc29e-278b-4786-aafa-e5697f53e19b' User entered '19 Nov 2020 16:40:04'	System	19 Nov 2020 23:40:08
	System	19 Nov 2020 23:40:08

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '16 Nov 2020 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '20 Nov 2020 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-11-26T20:57:01', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '215ff2f7-a2fc-4694-baaa-cc1cca56b4d3' User entered 'No (N)'	System	27 Nov 2020 03:57:10

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-11-26T20:57:06', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '215ff2f7-a2fc-4694-baaa-cc1cca56b4d3' User entered 'No (N)'	System	27 Nov 2020 03:57:10

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-11-26T20:57:08', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '215ff2f7-a2fc-4694-baaa-cc1cca56b4d3'	System	27 Nov 2020 03:57:10
User entered '26 Nov 2020 20:57:08'	System	27 Nov 2020 03:57:10



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-01T17:42:19', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '47dc402d-9f13-4d3b-b409-2ee3a42f7129' User entered 'No (N)'	System	02 Dec 2020 00:42:31
	System	02 Dec 2020 00:42:31

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-01T17:42:24', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '47dc402d-9f13-4d3b-b409-2ee3a42f7129' User entered 'No (N)'	System	02 Dec 2020 00:42:31
	System	02 Dec 2020 00:42:31

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-01T17:42:26', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '47dc402d-9f13-4d3b-b409-2ee3a42f7129' User entered '01 Dec 2020 17:42:26'	System	02 Dec 2020 00:42:31
	System	02 Dec 2020 00:42:31

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-09T13:18:05', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '175deb24-4550-48b1-a94c-382f2b88e5ae' User entered 'No (N)'	System	09 Dec 2020 20:18:13
	System	09 Dec 2020 20:18:13

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-09T13:18:07', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '175deb24-4550-48b1-a94c-382f2b88e5ae'	System	09 Dec 2020 20:18:13
User entered 'No (N)'	System	09 Dec 2020 20:18:13

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-09T13:18:10', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '175deb24-4550-48b1-a94c-382f2b88e5ae' User entered '09 Dec 2020 13:18:10'	System	09 Dec 2020 20:18:13
	System	09 Dec 2020 20:18:13

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-15T19:19:24', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '43b9475a-e5c0-4530-b9ef-1287e55251bf' User entered 'No (N)'	System	16 Dec 2020 02:19:49
	System	16 Dec 2020 02:19:49



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-15T19:19:26', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '43b9475a-e5c0-4530-b9ef-1287e55251bf' User entered 'Yes (Y)'	System	16 Dec 2020 02:19:49
	System	16 Dec 2020 02:19:49

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Please 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-15T19:19:34', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '43b9475a-e5c0-4530-b9ef-1287e55251bf'	System	16 Dec 2020 02:19:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Dec 2020 02:19:49

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-15T19:19:39', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '43b9475a-e5c0-4530-b9ef-1287e55251bf' User entered '15 Dec 2020 19:19:39'	System	16 Dec 2020 02:19:49
	System	16 Dec 2020 02:19:49

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-22T13:01:54', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'fa65387b-3ed0-4b45-aeed-76b9fb4b120c' User entered 'No (N)'	System	22 Dec 2020 20:02:09
	System	22 Dec 2020 20:02:09

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-22T13:02:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'fa65387b-3ed0-4b45-aeed-76b9fb4b120c' User entered 'No (N)'	System	22 Dec 2020 20:02:09
	System	22 Dec 2020 20:02:09



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-22T13:02:03', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'fa65387b-3ed0-4b45-aeed-76b9fb4b120c' User entered '22 Dec 2020 13:02:03'	System	22 Dec 2020 20:02:09
	System	22 Dec 2020 20:02:09

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-29T09:46:30', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f7b4cda5-6051-465e-9244-90d2543a3278' User entered 'No (N)'	System	29 Dec 2020 16:46:40
	System	29 Dec 2020 16:46:40

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-29T09:46:32', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f7b4cda5-6051-465e-9244-90d2543a3278' User entered 'No (N)'	System	29 Dec 2020 16:46:40
	System	29 Dec 2020 16:46:40

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2020-12-29T09:46:36', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'f7b4cda5-6051-465e-9244-90d2543a3278' User entered '29 Dec 2020 09:46:36'	System	29 Dec 2020 16:46:40
	System	29 Dec 2020 16:46:40

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-01-06T08:44:23', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'a23d541e-c104-48a3-bfdd-70f3f477422e' User entered 'No (N)'	System	06 Jan 2021 15:44:31

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-01-06T08:44:26', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'a23d541e-c104-48a3-bfdd-70f3f477422e' User entered 'No (N)'	System	06 Jan 2021 15:44:31

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-01-06T08:44:28', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'a23d541e-c104-48a3-bfdd-70f3f477422e' User entered '06 Jan 2021 08:44:28'	System	06 Jan 2021 15:44:31
	System	06 Jan 2021 15:44:31

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-01-13T15:54:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7c81ce98-a8f2-48a2-ab76-4a7a98cc6fb3'	System	13 Jan 2021 22:54:13
User entered 'No (N)'	System	13 Jan 2021 22:54:13

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-01-13T15:54:02', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7c81ce98-a8f2-48a2-ab76-4a7a98cc6fb3'	System	13 Jan 2021 22:54:13
User entered 'No (N)'	System	13 Jan 2021 22:54:13

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-01-13T15:54:10', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '7c81ce98-a8f2-48a2-ab76-4a7a98cc6fb3' User entered '13 Jan 2021 15:54:10'	System	13 Jan 2021 22:54:13

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-01-21T07:46:47', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6d68b17a-dd7b-436f-9a02-a22ec79405e7' User entered 'No (N)'	System	21 Jan 2021 14:46:56
	System	21 Jan 2021 14:46:56

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-01-21T07:46:50', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6d68b17a-dd7b-436f-9a02-a22ec79405e7'	System	21 Jan 2021 14:46:56
User entered 'No (N)'	System	21 Jan 2021 14:46:56



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-01-21T07:46:53', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6d68b17a-dd7b-436f-9a02-a22ec79405e7' User entered '21 Jan 2021 07:46:53'	System	21 Jan 2021 14:46:56
	System	21 Jan 2021 14:46:56

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-01-25T10:59:14', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'dd1d2970-fe04-41c1-b842-54bf9ac23807' User entered 'No (N)'	System	25 Jan 2021 17:59:23
	System	25 Jan 2021 17:59:23

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-01-25T10:59:17', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'dd1d2970-fe04-41c1-b842-54bf9ac23807' User entered 'No (N)'	System	25 Jan 2021 17:59:23

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-01-25T10:59:20', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'dd1d2970-fe04-41c1-b842-54bf9ac23807' User entered '25 Jan 2021 10:59:20'	System	25 Jan 2021 17:59:23
	System	25 Jan 2021 17:59:23

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-02-01T09:52:20', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '63705b87-2727-4f8c-afb5-3b390bfc26fa' User entered 'No (N)'	System	01 Feb 2021 16:52:29
	System	01 Feb 2021 16:52:29

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-02-01T09:52:22', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '63705b87-2727-4f8c-afb5-3b390bfc26fa' User entered 'No (N)'	System	01 Feb 2021 16:52:29

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-02-01T09:52:25', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '63705b87-2727-4f8c-afb5-3b390bfc26fa' User entered '01 Feb 2021 09:52:25'	System	01 Feb 2021 16:52:29
	System	01 Feb 2021 16:52:29

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-02-10T15:41:01', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '5bc07a17-4e52-4854-800e-02874bf6e8c7' User entered 'No (N)'	System	10 Feb 2021 22:41:13
	System	10 Feb 2021 22:41:13

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-02-10T15:41:03', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '5bc07a17-4e52-4854-800e-02874bf6e8c7'	System	10 Feb 2021 22:41:13
User entered 'No (N)'	System	10 Feb 2021 22:41:13

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-02-10T15:41:06', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '5bc07a17-4e52-4854-800e-02874bf6e8c7' User entered '10 Feb 2021 15:41:06'	System	10 Feb 2021 22:41:13
	System	10 Feb 2021 22:41:13

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-02-18T18:25:42', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'e47a0eca-d0e2-43bf-b617-1eab5e7ff94a' User entered 'No (N)'	System	19 Feb 2021 01:25:56

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-02-18T18:25:46', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'e47a0eca-d0e2-43bf-b617-1eab5e7ff94a' User entered 'No (N)'	System	19 Feb 2021 01:25:56



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-02-18T18:25:49', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'e47a0eca-d0e2-43bf-b617-1eab5e7ff94a' User entered '18 Feb 2021 18:25:49'	System	19 Feb 2021 01:25:56

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-02-24T16:09:08', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '9617246b-5b98-400e-aae5-c55fc76f5749' User entered 'No (N)'	System	24 Feb 2021 23:21:34
	System	24 Feb 2021 23:21:34

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-02-24T16:09:12', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '9617246b-5b98-400e-aae5-c55fc76f5749' User entered 'No (N)'	System	24 Feb 2021 23:21:34
	System	24 Feb 2021 23:21:34

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-02-24T16:09:14', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '9617246b-5b98-400e-aae5-c55fc76f5749' User entered '24 Feb 2021 16:09:14'	System	24 Feb 2021 23:21:34
	System	24 Feb 2021 23:21:34

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:14:46-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered 'Yes (Y)'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:14:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde'	System	02 Mar 2021 20:15:45
User entered 'No (N)'	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:14:58-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered 'Yes (Y)'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '0'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '1'	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '0'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '0'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '0'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '1'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '1'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '1'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '1'	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '0'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '0'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '0'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '0'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '0'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '0'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '0'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:20-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '0'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Please 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:23-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde'	System	02 Mar 2021 20:15:45
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:28-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered 'No (N)'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:15:32-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '354f8e32-c206-42a0-b609-0b666d1e1cde' User entered '02 Mar 2021 13:15:32'	System	02 Mar 2021 20:15:45
	System	02 Mar 2021 20:15:45

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-08T06:17:51-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3cebc3cb-848c-497d-a611-4684a4c82735' User entered 'No (N)'	System	08 Mar 2021 13:18:09
	System	08 Mar 2021 13:18:09

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-08T06:17:53-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3cebc3cb-848c-497d-a611-4684a4c82735'	System	08 Mar 2021 13:18:09
User entered 'No (N)'	System	08 Mar 2021 13:18:09

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-08T06:17:56-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '3cebc3cb-848c-497d-a611-4684a4c82735' User entered '08 Mar 2021 06:17:56'	System	08 Mar 2021 13:18:09
	System	08 Mar 2021 13:18:09

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-18T13:23:17-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '66093ba5-687c-42da-a5fd-50ee7918eb6b'	System	18 Mar 2021 20:23:24
User entered 'No (N)'	System	18 Mar 2021 20:23:24

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-18T13:23:19-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '66093ba5-687c-42da-a5fd-50ee7918eb6b' User entered 'No (N)'	System	18 Mar 2021 20:23:24
	System	18 Mar 2021 20:23:24

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-18T13:23:22-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '66093ba5-687c-42da-a5fd-50ee7918eb6b' User entered '18 Mar 2021 13:23:22'	System	18 Mar 2021 20:23:24
	System	18 Mar 2021 20:23:24

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-22T05:27:44-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c5b82ceb-5e80-466a-ad00-ebb66e71d011'	System	22 Mar 2021 12:28:00
User entered 'No (N)'	System	22 Mar 2021 12:28:00

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-22T05:27:47-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c5b82ceb-5e80-466a-ad00-ebb66e71d011' User entered 'No (N)'	System	22 Mar 2021 12:28:00
	System	22 Mar 2021 12:28:00

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-22T05:27:49-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'c5b82ceb-5e80-466a-ad00-ebb66e71d011' User entered '22 Mar 2021 05:27:49'	System	22 Mar 2021 12:28:00
	System	22 Mar 2021 12:28:00

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-29T17:38:10-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '665830b7-88cb-42b4-ae0d-8b788181a60b'	System	30 Mar 2021 00:38:22
User entered 'No (N)'	System	30 Mar 2021 00:38:22

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-29T17:38:16-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '665830b7-88cb-42b4-ae0d-8b788181a60b'	System	30 Mar 2021 00:38:22
User entered 'No (N)'	System	30 Mar 2021 00:38:22



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-29T17:38:19-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '665830b7-88cb-42b4-ae0d-8b788181a60b' User entered '29 Mar 2021 17:38:19'	System	30 Mar 2021 00:38:22

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-05T05:18:11-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '644a3094-1f9e-4d32-92f1-f100f9cecd4' User entered 'No (N)'	System	05 Apr 2021 12:18:21
	System	05 Apr 2021 12:18:21

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-05T05:18:15-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '644a3094-1f9e-4d32-92f1-f100f9cecd4'	System	05 Apr 2021 12:18:21
User entered 'No (N)'	System	05 Apr 2021 12:18:21

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-05T05:18:18-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '644a3094-1f9e-4d32-92f1-f100f9cecd4'	System	05 Apr 2021 12:18:21
User entered '05 Apr 2021 05:18:18'	System	05 Apr 2021 12:18:21

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-12T21:04:11-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'edf014c5-f5fe-456c-bf28-9ad0077c2743'	System	13 Apr 2021 04:05:28
User entered 'No (N)'	System	13 Apr 2021 04:05:28

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-12T21:04:14-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'edf014c5-f5fe-456c-bf28-9ad0077c2743'	System	13 Apr 2021 04:05:28
User entered 'No (N)'	System	13 Apr 2021 04:05:28

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-12T21:04:18-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: 'edf014c5-f5fe-456c-bf28-9ad0077c2743'	System	13 Apr 2021 04:05:28
User entered '12 Apr 2021 21:04:18'	System	13 Apr 2021 04:05:28

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:22-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered 'Yes (Y)'	System	19 Apr 2021 12:14:15
	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:26-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered 'No (N)'	System	19 Apr 2021 12:14:15
	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:29-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered 'Yes (Y)'	System	19 Apr 2021 12:14:15
	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '0'	System	19 Apr 2021 12:14:15
	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '0'	System	19 Apr 2021 12:14:15
	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '1'	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '0'	System	19 Apr 2021 12:14:15
	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '1'	System	19 Apr 2021 12:14:15



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '1'	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '0'	System	19 Apr 2021 12:14:15
	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '0'	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '1'	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '0'	System	19 Apr 2021 12:14:15
	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '1'	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '1'	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '1'	System	19 Apr 2021 12:14:15



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '1'	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '0'	System	19 Apr 2021 12:14:15
	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '0'	System	19 Apr 2021 12:14:15
	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:48-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '0'	System	19 Apr 2021 12:14:15
	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Please 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:53-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d'	System	19 Apr 2021 12:14:15
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:13:59-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d'	System	19 Apr 2021 12:14:15
User entered 'No (N)'	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-19T05:14:03-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '77f58994-184d-47eb-8dfb-a2adaa35d53d' User entered '19 Apr 2021 05:14:03'	System	19 Apr 2021 12:14:15
	System	19 Apr 2021 12:14:15

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-28T08:15:56-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6b003e10-801f-41ed-96e0-36487d9117fd' User entered 'No (N)'	System	29 Apr 2021 02:25:38
	System	29 Apr 2021 02:25:38

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

Have you been exposed to someone with 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 (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-28T08:15:58-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6b003e10-801f-41ed-96e0-36487d9117fd' User entered 'No (N)'	System	29 Apr 2021 02:25:38

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-04-28T08:16:00-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '6b003e10-801f-41ed-96e0-36487d9117fd' User entered '28 Apr 2021 08:16:00'	System	29 Apr 2021 02:25:38
	System	29 Apr 2021 02:25:38

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:37:25



**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '17 Oct 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '21 Oct 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '24 Oct 2022 00:01'	System	19 Nov 2020 20:37:25



**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '28 Oct 2022 23:59'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '31 Oct 2022 00:01'	System	19 Nov 2020 20:37:25

**US3192575**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Aug 2021 22:03:43**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:37:25
Amendment Manager: User entered '04 Nov 2022 23:59'	System	19 Nov 2020 20:37:25

US3192575

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:03:43

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)	26 Apr 2021 04:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:14:30-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '4ad212aa-c163-47d5-8ec8-229a9ef5c31a' User entered 'No (N)'	System	02 Mar 2021 20:14:40
	System	02 Mar 2021 20:14:40

**US3192575**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 04:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F5147379-BF28-4A41-9A52-1988DBD5FECC)', Time: '2021-03-02T13:14:36-07:00', User OID: 'PatientReportedOutcome (US3192575)', ODM File OID: '4ad212aa-c163-47d5-8ec8-229a9ef5c31a' User entered '02 Mar 2021 13:14:36'	System	02 Mar 2021 20:14:40
	System	02 Mar 2021 20:14:40

**US3192575**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:28:07
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	25 Nov 2020 16:58:59

**US3192575**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:28:07
User entered '24 Nov 2020'	Amanda Hermosillo	25 Nov 2020 16:58:59



**US3192575**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:28:07
User entered 'Contact Made (CONTACT MADE)'	Amanda Hermosillo (b) (4)	25 Nov 2020 16:58:59

**US3192575**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:28:07
User entered empty.	Amanda Hermosillo (b) (4)	25 Nov 2020 16:58:59

**US3192575**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:28:07
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	25 Nov 2020 16:59:02

**US3192575**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:11:34
User entered 'I'	System	25 Nov 2020 16:59:02

**US3192575**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:27:34

**US3192575**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:27:34

**US3192575**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:27:34

**US3192575**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:27:34



**US3192575**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Dec 2020 15:27:39

**US3192575**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User entered '1'	System	30 Dec 2020 15:27:39

**US3192575**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'No (N)'	Saysamone Banks (b) (4)	25 Mar 2021 00:38:59

**US3192575**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:38:59
	(b) (4)	

**US3192575**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	Saysamone Banks (b) (4)	25 Mar 2021 00:38:59

**US3192575**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	Saysamone Banks (b) (4)	25 Mar 2021 00:38:59

US3192575

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:39:11
	(b) (4)	

**US3192575**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User entered 'I'	System	25 Mar 2021 00:39:11



**US3192575**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'No (N)'	Saysamone Banks (b) (4)	25 Mar 2021 00:39:38

**US3192575**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	Saysamone Banks (b) (4)	25 Mar 2021 00:39:38

**US3192575**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:39:38
	(b) (4)	

**US3192575**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	Saysamone Banks (b) (4)	25 Mar 2021 00:39:38

**US3192575**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:39:47
	(b) (4)	

**US3192575**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:52:32
User entered '1'	System	25 Mar 2021 00:39:47

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	Saysamone Banks (b) (4)	25 Mar 2021 00:42:20

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '24 Mar 2021'	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:42:20
	(b) (4)	



**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Clinic (Clinic)'	Saysamone Banks (b) (4)	25 Mar 2021 00:42:20

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User entered 'VISIT4'	System	25 Mar 2021 00:42:20

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	(b) (4)	
	Amanda Hermosillo	02 Apr 2021 17:54:29
	(b) (4)	

US3192575

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '24 Mar 2021'	Amanda Hermosillo (b) (4)	02 Apr 2021 17:54:29

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '17:08'	Amanda Hermosillo (b) (4)	02 Apr 2021 17:54:29

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User entered '24 Mar 2021 17:08'	System	02 Apr 2021 17:54:29

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '98.3' F	Amanda Hermosillo (b) (4)	02 Apr 2021 17:54:29

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Oral (Oral)'	Amanda Hermosillo (b) (4)	02 Apr 2021 17:54:29



**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	Amanda Hermosillo (b) (4)	02 Apr 2021 17:54:29

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '66'	Amanda Hermosillo (b) (4)	02 Apr 2021 17:54:29

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User entered 'bpm'	System	02 Apr 2021 17:54:29

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '14'	Amanda Hermosillo (b) (4)	02 Apr 2021 17:54:29

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User entered 'breaths/min'	System	02 Apr 2021 17:54:29

US3192575

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:03:43

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '108'	Amanda Hermosillo (b) (4)	02 Apr 2021 17:54:29

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User entered 'mmHg'	System	02 Apr 2021 17:54:29

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '73'	Amanda Hermosillo (b) (4)	02 Apr 2021 17:54:29



**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User entered 'mmHg'	System	02 Apr 2021 17:54:29

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:03:43**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'No (N)'	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:42:27
	(b) (4)	

US3192575

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:03:43

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:42:27
	(b) (4)	

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'No (N)'	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:42:33
	(b) (4)	

US3192575

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:43

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:42:33
	(b) (4)	

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	Saysamone Banks (b) (4)	25 Mar 2021 00:42:33



**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User entered empty.	System	25 Mar 2021 00:42:33

US3192575

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:42:37
	(b) (4)	

**US3192575**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:55:21
User entered '1'	System	25 Mar 2021 00:42:37

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Jan 2021 21:12:56

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '21 Jan 2021'	Zoe Sesma (b) (4)	21 Jan 2021 21:12:56

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Clinic (Clinic)'	Zoe Sesma (b) (4)	21 Jan 2021 21:12:56

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'UNBLND_DECIDE'	System	21 Jan 2021 21:12:56

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:03:43

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '21 Jan 2021'	Zoe Sesma (b) (4)	21 Jan 2021 21:13:09



**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:03:43**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 17:59:10
User entered '0'	Damaris Atondo (b) (4)	09 Apr 2021 20:25:33
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:19:28

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:03:43**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Jan 2021 21:13:09

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:03:43

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User closed query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).		19 Apr 2021 15:13:38
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 17:59:10
Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' answered with 'updated' (Site from DM).	(b) (4) Damaris Atondo (b) (4)	09 Apr 2021 20:25:49
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	09 Apr 2021 20:25:33
User opened query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 18:48:13
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:19:28

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:03:43**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '21 Jan 2021'	Zoe Sesma (b) (4)	21 Jan 2021 21:13:09

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 22:03:43

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Placebo (Placebo)'	Zoe Sesma (b) (4)	21 Jan 2021 21:13:09

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:03:43**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Placebo (Placebo)'	Zoe Sesma (b) (4)	21 Jan 2021 21:13:09

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:03:43**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Placebo (Placebo)'	Zoe Sesma (b) (4)	21 Jan 2021 21:13:09

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:03:43**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Jan 2021 21:13:09



**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:03:43**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '1'	System	21 Jan 2021 21:13:09

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'I'	System	21 Jan 2021 21:13:09

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:03:43**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '67' in	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:03:43

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '153' lb	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:03:43**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '24.01329'	System	21 Jan 2021 21:14:16
DataPoint set to visible.	System	21 Jan 2021 21:13:09

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:03:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '67' in	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:03:43**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '153' lb	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:03:43**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '24.01329'	System	21 Jan 2021 21:14:16
DataPoint set to visible.	System	21 Jan 2021 21:13:09



**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User accepted default value 'Pre-Dose (PREDOSE)'	Zoe Sesma (b) (4) (b) (4)	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '21 Jan 2021'	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '13:30'	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '21 Jan 2021 13:30'	System	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '99' F	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Oral (Oral)'	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16



**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '74'	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'bpm'	System	21 Jan 2021 21:14:16

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '12'	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'breaths/min'	System	21 Jan 2021 21:14:16

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '120'	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'mmHg'	System	21 Jan 2021 21:14:16

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:03:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '73'	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'mmHg'	System	21 Jan 2021 21:14:16



US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:03:43

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '67' in	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:03:43**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '153' lb	Zoe Sesma (b) (4)	21 Jan 2021 21:14:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 11 Aug 2021 22:03:43**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '24.01329'	System	21 Jan 2021 21:14:16
DataPoint set to visible.	System	21 Jan 2021 21:13:09

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User accepted default value 'Post-Dose (POSTDOSE)'	Zoe Sesma (b) (4) (b) (4)	21 Jan 2021 22:44:46

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Jan 2021 22:44:46

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '21 Jan 2021'	Zoe Sesma (b) (4)	21 Jan 2021 22:44:46

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '14:36'	Zoe Sesma (b) (4)	21 Jan 2021 22:44:46

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '21 Jan 2021 14:36'	System	21 Jan 2021 22:44:46



**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '98.8' F	Zoe Sesma (b) (4)	21 Jan 2021 22:44:46

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Oral (Oral)'	Zoe Sesma (b) (4)	21 Jan 2021 22:44:46

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	Zoe Sesma (b) (4)	21 Jan 2021 22:44:46

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '65'	Zoe Sesma (b) (4)	21 Jan 2021 22:44:46

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'bpm'	System	21 Jan 2021 22:44:46

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '14'	Zoe Sesma (b) (4)	21 Jan 2021 22:44:46

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'breaths/min'	System	21 Jan 2021 22:44:46

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '111'	Zoe Sesma (b) (4)	21 Jan 2021 22:44:46



**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'mmHg'	System	21 Jan 2021 22:44:46

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:03:43

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '82'	Zoe Sesma (b) (4)	21 Jan 2021 22:44:46

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'mmHg'	System	21 Jan 2021 22:44:46

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:03:43**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Jan 2021 21:14:28

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:03:43**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '21 Jan 2021'	Zoe Sesma (b) (4)	21 Jan 2021 21:14:28

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:03:43

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Jan 2021 21:16:16

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:03:43

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '21 Jan 2021'	Zoe Sesma (b) (4)	21 Jan 2021 21:16:16

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:03:43

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Urine (URINE)'	Zoe Sesma (b) (4)	21 Jan 2021 21:16:16



US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:03:43

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Negative (NEGATIVE)'	Zoe Sesma (b) (4)	21 Jan 2021 21:16:16

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:03:43

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'No (N)'	Zoe Sesma (b) (4)	21 Jan 2021 21:16:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	Zoe Sesma (b) (4)	21 Jan 2021 21:16:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	Zoe Sesma (b) (4)	21 Jan 2021 21:16:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered empty.	System	21 Jan 2021 21:16:16

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Jan 2021 21:20:33

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Zoe Sesma (b) (4)	21 Jan 2021 21:20:33

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Zoe Sesma (b) (4)	21 Jan 2021 21:20:33



**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'mRNA-1273'	System	21 Jan 2021 21:20:33
DataPoint set to visible.	System	21 Jan 2021 21:13:09

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '21 Jan 2021'	Zoe Sesma (b) (4)	21 Jan 2021 21:20:33

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '14:05'	Zoe Sesma (b) (4)	21 Jan 2021 21:20:33

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '21 Jan 2021 14:05'	System	21 Jan 2021 21:20:33

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Left Arm (LEFT ARM)'	Zoe Sesma (b) (4)	21 Jan 2021 21:20:33

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'ONCE'	System	21 Jan 2021 21:20:33

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'INTRAMUSCULAR'	System	21 Jan 2021 21:20:33

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:43

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Jan 2021 21:20:42



US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:03:43

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '21 Jan 2021'	Zoe Sesma (b) (4)	21 Jan 2021 21:20:42

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '13:38'	Zoe Sesma (b) (4)	21 Jan 2021 21:20:42

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '21 Jan 2021 13:38'	System	21 Jan 2021 21:20:42

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:03:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Jan 2021 21:20:51

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:03:43**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '21 Jan 2021'	Zoe Sesma (b) (4)	21 Jan 2021 21:20:51

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:03:43**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '13:39'	Zoe Sesma (b) (4)	21 Jan 2021 21:20:51

**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Aug 2021 22:03:43**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '21 Jan 2021 13:39'	System	21 Jan 2021 21:20:51

US3192575

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:03:43

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Jan 2021 21:20:54



**US3192575**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '1'	System	21 Jan 2021 21:20:54

**US3192575**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	Saysamone Banks (b) (4)	02 Feb 2021 16:25:20

**US3192575**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '31 Jan 2021'	(b) (4) Saysamone Banks (b) (4)	02 Feb 2021 16:25:20

**US3192575**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Saysamone Banks (b) (4)	02 Feb 2021 16:25:20

**US3192575**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	02 Feb 2021 16:25:20
	(b) (4)	

**US3192575**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	(b) (4) Saysamone Banks (b) (4)	02 Feb 2021 16:24:51

**US3192575**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'I'	System	02 Feb 2021 16:24:51

**US3192575**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '1'	System	02 Feb 2021 16:24:51
DataPoint set to visible.	System	02 Feb 2021 16:24:51



**US3192575**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	Tianna Young (b) (4)	25 Feb 2021 00:03:36

**US3192575**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '24 Feb 2021'	Tianna Young (b) (4)	25 Feb 2021 00:03:36

**US3192575**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Clinic (Clinic)'	Tianna Young (b) (4)	25 Feb 2021 00:03:36

**US3192575**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'OLD29'	System	25 Feb 2021 00:03:36

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User accepted default value 'Pre-Dose (PREDOSE)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 00:04:41

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	Tianna Young (b) (4)	25 Feb 2021 00:04:41

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '24 Feb 2021'	Tianna Young (b) (4)	25 Feb 2021 00:04:41

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '15:40'	Tianna Young (b) (4)	25 Feb 2021 00:04:41



**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '24 Feb 2021 15:40'	System	25 Feb 2021 00:04:41

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '98.6' F	Tianna Young (b) (4)	25 Feb 2021 00:04:41

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Oral (Oral)'	Tianna Young (b) (4)	25 Feb 2021 00:04:41

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Tianna Young (b) (4)	25 Feb 2021 00:04:41

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '62'	Tianna Young (b) (4)	25 Feb 2021 00:04:41

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'bpm'	System	25 Feb 2021 00:04:41

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '12'	Tianna Young (b) (4)	25 Feb 2021 00:04:41

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'breaths/min'	System	25 Feb 2021 00:04:41



**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '109'	Tianna Young (b) (4)	25 Feb 2021 00:04:41

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'mmHg'	System	25 Feb 2021 00:04:41

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '70'	Tianna Young (b) (4)	25 Feb 2021 00:04:41

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'mmHg'	System	25 Feb 2021 00:04:41

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User accepted default value 'Post-Dose (POSTDOSE)'	Tianna Young (b) (4) (b) (4)	25 Feb 2021 00:05:13

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	Tianna Young (b) (4)	25 Feb 2021 00:05:13

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '24 Feb 2021'	Tianna Young (b) (4)	25 Feb 2021 00:05:13

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '16:33'	Tianna Young (b) (4)	25 Feb 2021 00:05:13



**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '24 Feb 2021 16:33'	System	25 Feb 2021 00:05:13

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '98.7' F	Tianna Young (b) (4)	25 Feb 2021 00:05:13

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Oral (Oral)'	Tianna Young (b) (4)	25 Feb 2021 00:05:13

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Tianna Young (b) (4)	25 Feb 2021 00:05:13

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '54'	Tianna Young (b) (4)	25 Feb 2021 00:05:13

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'bpm'	System	25 Feb 2021 00:05:13

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '14'	Tianna Young (b) (4)	25 Feb 2021 00:05:13

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'breaths/min'	System	25 Feb 2021 00:05:13



**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '105'	Tianna Young (b) (4)	25 Feb 2021 00:05:13

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'mmHg'	System	25 Feb 2021 00:05:13

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '71'	Tianna Young (b) (4)	25 Feb 2021 00:05:13

**US3192575**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'mmHg'	System	25 Feb 2021 00:05:13

**US3192575**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:03:43**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	Tianna Young (b) (4)	25 Feb 2021 00:03:42

**US3192575**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:03:43**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '24 Feb 2021'	Tianna Young (b) (4)	25 Feb 2021 00:03:42

**US3192575**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	Tianna Young (b) (4)	25 Feb 2021 00:04:08

**US3192575**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

**Date of test (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '24 Feb 2021'	Tianna Young (b) (4)	25 Feb 2021 00:04:08



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**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Urine (URINE)'	Tianna Young (b) (4)	25 Feb 2021 00:04:08

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**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Negative (NEGATIVE)'	Tianna Young (b) (4)	25 Feb 2021 00:04:08

**US3192575**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	Tianna Young (b) (4)	25 Feb 2021 00:04:08

**US3192575**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Tianna Young (b) (4)	25 Feb 2021 00:04:08

**US3192575**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Tianna Young (b) (4)	25 Feb 2021 00:04:08

**US3192575**

**Folder: OL-D29 (1)**

**Form: Pregnancy Test**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered empty.	System	25 Feb 2021 00:04:08

**US3192575**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	Tianna Young (b) (4)	25 Feb 2021 00:03:54

**US3192575**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Tianna Young (b) (4)	25 Feb 2021 00:03:54



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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Tianna Young (b) (4)	25 Feb 2021 00:03:54

**US3192575**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'mRNA-1273'	System	25 Feb 2021 00:03:54
DataPoint set to visible.	System	02 Feb 2021 16:24:51

US3192575

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '24 Feb 2021'	Tianna Young (b) (4)	25 Feb 2021 00:03:54

**US3192575**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '16:03'	Tianna Young (b) (4)	25 Feb 2021 00:03:54

**US3192575**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '24 Feb 2021 16:03'	System	25 Feb 2021 00:03:54

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Left Arm (LEFT ARM)'	Tianna Young (b) (4)	25 Feb 2021 00:03:54

**US3192575**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 11 Aug 2021 22:03:43**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'ONCE'	System	25 Feb 2021 00:03:54

US3192575

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:03:43

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 00:03:54



**US3192575**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	Tianna Young (b) (4)	25 Feb 2021 00:03:59

**US3192575**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '1'	System	25 Feb 2021 00:03:59

**US3192575**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	Damaris Atondo (b) (4)	13 Mar 2021 00:23:30

**US3192575**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered '3 Mar 2021'	Damaris Atondo (b) (4)	13 Mar 2021 00:23:30

**US3192575**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Damaris Atondo (b) (4)	13 Mar 2021 00:23:30

**US3192575**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Aug 2021 22:03:43**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered empty.	Damaris Atondo (b) (4)	13 Mar 2021 00:23:30

**US3192575**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:18:01
User entered 'Yes (Y)'	Damaris Atondo (b) (4)	13 Mar 2021 00:23:36

**US3192575**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Aug 2021 22:03:43**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'I'	System	13 Mar 2021 00:23:36



**US3192575**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	(b) (4) Saysamone Banks (b) (4)	25 Mar 2021 00:36:45

**US3192575**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '24 Mar 2021'	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:36:45
	(b) (4)	

**US3192575**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Clinic (Clinic)'	(b) (4) Saysamone Banks (b) (4)	25 Mar 2021 00:36:45

**US3192575**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Aug 2021 22:03:43**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'OLD57'	System	25 Mar 2021 00:36:45

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	Saysamone Banks (b) (4)	25 Mar 2021 00:37:54

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '24 Mar 2021'	(b) (4) Saysamone Banks (b) (4)	25 Mar 2021 00:37:54

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '17:08'	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:37:54
	(b) (4)	

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '24 Mar 2021 17:08'	System	25 Mar 2021 00:37:54



**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '98.3' F	Saysamone Banks (b) (4)	25 Mar 2021 00:37:54

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Oral (Oral)'	(b) (4) Saysamone Banks (b) (4)	25 Mar 2021 00:37:54

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:37:54
	(b) (4)	

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '66'	Saysamone Banks (b) (4)	25 Mar 2021 00:37:54

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'bpm'	System	25 Mar 2021 00:37:54

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '14'	Saysamone Banks (b) (4)	25 Mar 2021 00:37:54

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'breaths/min'	System	25 Mar 2021 00:37:54

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '108'	Saysamone Banks (b) (4)	25 Mar 2021 00:37:54



**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'mmHg'	System	25 Mar 2021 00:37:54

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '73'	Saysamone Banks (b) (4)	25 Mar 2021 00:37:54

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered 'mmHg'	System	25 Mar 2021 00:37:54

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04

**US3192575**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Aug 2021 22:03:43**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04

**US3192575**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:03:43**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:38:02
	(b) (4)	

**US3192575**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 11 Aug 2021 22:03:43**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	25 Mar 2021 00:38:02
	(b) (4)	

**US3192575**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	(b) (4) Saysamone Banks (b) (4)	25 Mar 2021 00:38:15



**US3192575**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '24 Mar 2021'	(b) (4) Saysamone Banks (b) (4)	25 Mar 2021 00:38:15

**US3192575**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '17:14'	(b) (4) Saysamone Banks (b) (4)	25 Mar 2021 00:38:15

**US3192575**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Aug 2021 22:03:43**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:04
User entered '24 Mar 2021 17:14'	System	25 Mar 2021 00:38:15

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Aug 2021 22:03:43**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:23:31
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
Signature has been broken.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:15:40
User entered 'Yes (Y)' reason for change: Data Entry Error		14 Mar 2021 16:15:40
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 16:29:53
User entered 'No (N)'	(b) (4) Yvonne De Los Reyes (b) (4)	24 Sep 2020 05:42:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:43

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Pain injection site - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Mar 2021 16:35:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Mar 2021 16:35:39
Data point term sent to Coder	System	14 Mar 2021 16:16:59
User entered 'sore arm at injection site'	(b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 21:07:32
Query 'Data is required. Please provide.' answered with 'patient did not disclose' (Site from System).		14 Mar 2021 16:16:53
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Mar 2021 16:16:44
User entered empty.	(b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

US3192575

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:03:43

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 21:07:34
Query 'Data is required. Please provide.' answered with 'patient did not disclose' (Site from System).		14 Mar 2021 16:16:57
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Mar 2021 16:16:44
User entered empty.	(b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Mar 2021 16:16:44

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\\23.0.	Coder Import (b) (4)	14 Mar 2021 16:21:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Mar 2021 16:21:36
Data point term sent to Coder	System	14 Mar 2021 16:21:00
User entered 'chills'	(b) (4), (b) (6)	14 Mar 2021 16:20:14



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Mar 2021 21:07:58
Query 'Data is required. Please provide.' answered with 'patient did not disclose' (Site from System).	(b) (4), (b) (6)	14 Mar 2021 16:20:19
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Mar 2021 16:20:14
User entered empty.	(b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User entered empty.	System	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Mar 2021 21:08:01
Query 'Data is required. Please provide.' answered with 'patient did not disclose' (Site from System).	(b) (4), (b) (6)	14 Mar 2021 16:20:23
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Mar 2021 16:20:14
User entered empty.	(b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User entered empty.	System	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:43

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User closed query 'Per CDM: Since participant received second dose of IP during OL-D29 visit on 24Feb2021, it is unexpected that AE#2 with a start date of 24Feb2021 would have "Action taken with IP" recorded as "IP Withdrawn". Please review and reconcile. Thank you. ' (Site from DM).		20 Apr 2021 16:03:56
Query 'Per CDM: Since participant received second dose of IP during OL-D29 visit on 24Feb2021, it is unexpected that AE#2 with a start date of 24Feb2021 would have "Action taken with IP" recorded as "IP Withdrawn". Please review and reconcile. Thank you. ' answered with 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	12 Apr 2021 18:33:45
User opened query 'Per CDM: Since participant received second dose of IP during OL-D29 visit on 24Feb2021, it is unexpected that AE#2 with a start date of 24Feb2021 would have "Action taken with IP" recorded as "IP Withdrawn". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 14:37:09
User signature succeeded.	John McGettigan (b) (4) (b) (4)	20 Mar 2021 17:15:49
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	(b) (4), (b) (6)	14 Mar 2021 16:20:14

US3192575

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:03:43

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).		13 Apr 2021 07:04:12
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 00:43:14
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 00:43:06
User entered '0' reason for change: Data Entry Error		07 Apr 2021 00:43:06
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).		31 Mar 2021 07:56:39
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '1'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 00:43:06
User entered '1' reason for change: Data Entry Error		07 Apr 2021 00:43:06
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User entered '0'	System	14 Mar 2021 16:20:14



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07
User entered '0'	System	14 Mar 2021 16:20:14

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:07

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	Coder Import (b) (4)	14 Mar 2021 16:22:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Mar 2021 16:22:36
Data point term sent to Coder	System	14 Mar 2021 16:22:00
User entered 'body aches'	(b) (4), (b) (6)	14 Mar 2021 16:21:10

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 21:08:14
Query 'Data is required. Please provide.' answered with 'patient did not disclose' (Site from System).		14 Mar 2021 16:21:15
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Mar 2021 16:21:10
User entered empty.	(b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User entered empty.	System	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Mar 2021 21:08:28
Query 'Data is required. Please provide.' answered with 'patient did not disclose' (Site from System).	(b) (4), (b) (6)	14 Mar 2021 16:21:19
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Mar 2021 16:21:10
User entered empty.	(b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User entered empty.	System	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

US3192575

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:03:43

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User closed query 'Per DM CLR: Other Action Take = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).		13 Apr 2021 07:04:19
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 00:44:01
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 00:43:41
User entered '0' reason for change: Data Entry Error		07 Apr 2021 00:43:41
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).		31 Mar 2021 07:56:49
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '1'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 00:43:41
User entered '1' reason for change: Data Entry Error		07 Apr 2021 00:43:41
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User entered '0'	System	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User entered '0'	System	14 Mar 2021 16:21:10

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12

US3192575

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of TENSION HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 07:04:26
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of TENSION HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' answered with 'Noting that the patient got her 2nd dose the same day headache the same day she got her headache. its a reaction from the vaccine' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 00:46:30
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of TENSION HEADACHES. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 07:57:05
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	14 Mar 2021 16:23:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Mar 2021 16:23:37
Data point term sent to Coder	System	14 Mar 2021 16:23:04
User entered 'headache'	(b) (4), (b) (6)	14 Mar 2021 16:22:29



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '24 Feb 2021'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Mar 2021 21:08:48
Query 'Data is required. Please provide.' answered with 'patient did not disclose' (Site from System).	(b) (4), (b) (6)	14 Mar 2021 16:22:34
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Mar 2021 16:22:29
User entered empty.	(b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User entered empty.	System	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29



US3192575

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Mar 2021 21:08:51
Query 'Data is required. Please provide.' answered with 'patient did not disclose' (Site from System).	(b) (4), (b) (6)	14 Mar 2021 16:22:37
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Mar 2021 16:22:29
User entered empty.	(b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User entered empty.	System	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

US3192575

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:43

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

US3192575

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:43

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

US3192575

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

US3192575

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:03:43

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).		13 Apr 2021 07:04:29
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 00:54:26
Signature has been broken.	(b) (4), (b) (6)	07 Apr 2021 00:54:18
User entered '0' reason for change: Data Entry Error		07 Apr 2021 00:54:18
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication #6 recorded that matches this AE during this timeframe. Please review and update AE eCRF as appropriate. ' (Site from DM).		31 Mar 2021 07:56:58
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '1'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
Signature has been broken.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 00:54:18
User entered '1' reason for change: Data Entry Error		07 Apr 2021 00:54:18
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User entered '0'	System	14 Mar 2021 16:22:29



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12
User entered '0'	System	14 Mar 2021 16:22:29

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:03:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User closed query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).		13 Apr 2021 07:04:35
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site rash, LLT: Rash injection site - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:21:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 06:21:40
User signature succeeded.	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:17:41
Data point term sent to Coder	System	07 Apr 2021 00:54:03
Query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 00:53:51
Coding entries removed.	(b) (4), (b) (6)	07 Apr 2021 00:53:39
Signature has been broken.		07 Apr 2021 00:53:39
User entered 'RASH AT INJECTION SITE non-urticarial' reason for change: Data Entry Error		07 Apr 2021 00:53:39
User opened query 'Per DM CLR: Please review AE and please update to specify if this is URTICARIAL or NON-URTICARIAL. Please update and reconcile with applicable eCRFs so there would be an appropriate match. Otherwise, clarify. ' (Site from DM).		31 Mar 2021 07:57:15
User signature succeeded.	John McGettigan (b) (4) (b) (4)	20 Mar 2021 17:15:49

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:03:43

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site rash, LLT: Rash injection site - version MedDRA\\23.0.	Coder Import (b) (4)	14 Mar 2021 16:24:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Mar 2021 16:24:36
Data point term sent to Coder	System	14 Mar 2021 16:24:04
User entered 'rash at injection site'	(b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '25 Feb 2021'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 21:09:30
Query 'Data is required. Please provide.' answered with 'patient did not disclose' (Site from System).		14 Mar 2021 16:23:29
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Mar 2021 16:23:24
User entered empty.	(b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User entered empty.	System	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '28 Feb 2021'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:03:43

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	15 Mar 2021 21:09:36
Query 'Data is required. Please provide.' answered with 'patient did not disclose' (Site from System).	(b) (4), (b) (6)	14 Mar 2021 16:23:39
User opened query 'Data is required. Please provide.' (Site from System).	System	14 Mar 2021 16:23:24
User entered empty.	(b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User entered empty.	System	14 Mar 2021 16:23:24

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:03:43

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
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	14 Mar 2021 16:23:42
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Mar 2021 16:23:42
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Mar 2021 16:23:24
User entered empty.	(b) (4), (b) (6)	14 Mar 2021 16:23:24



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24



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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Aug 2021 22:03:43

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Related (RELATED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User signature succeeded.	John McGettigan (b) (4)	20 Mar 2021 17:15:49
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User entered '0'	System	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14
User entered '0'	System	14 Mar 2021 16:23:24

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:14

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26



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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Aug 2021 22:03:43

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site tenderness - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 17:09:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 17:09:39
Data point term sent to Coder	System	07 Apr 2021 17:08:55
User entered 'Tenderness at injection site'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '22 Jan 2021'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User closed query 'Data is required. Please provide.' (Site from System).		20 Apr 2021 16:02:11
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System).	(b) (4)	
	Yvonne De Los Reyes	07 Apr 2021 17:08:18
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	System	07 Apr 2021 17:08:12
User entered empty.	Yvonne De Los Reyes	07 Apr 2021 17:08:12
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User entered empty.	System	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

**If not Ongoing, end date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '23 Jan 2021'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User closed query 'Data is required. Please provide.' (Site from System).		20 Apr 2021 16:02:13
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
Query 'Data is required. Please provide.' answered with 'not collected' (Site from System).	(b) (4)	
	Yvonne De Los Reyes	07 Apr 2021 17:08:23
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	
	System	07 Apr 2021 17:08:12
User entered empty.	Yvonne De Los Reyes	07 Apr 2021 17:08:12
	(b) (4)	

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User entered empty.	System	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Grade 1/Mild (Grade 1/Mild)'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '0'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '0'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '0'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '0'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '0'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '0'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Related (RELATED)'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Not Applicable (NOT APPLICABLE)'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '0'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'I'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '0'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:12



**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User entered '0'	System	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26
User entered '0'	System	07 Apr 2021 17:08:12

**US3192575**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:40:26

US3192575

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 11 Aug 2021 22:03:43**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:23:31
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	05 Sep 2020 12:55:53

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:43

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
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: JUNEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 10:31:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Feb 2021 10:31:44
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: JUNEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 12:58:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Sep 2020 12:58:37
Data point term sent to Coder User entered 'JUNEL'	System Norma Barrientos (b) (4)	05 Sep 2020 12:57:55 05 Sep 2020 12:56:59

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	05 Sep 2020 12:56:59
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'BIRTH CONTROL'	Norma Barrientos (b) (4)	05 Sep 2020 12:56:59

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered '1/20'	Norma Barrientos (b) (4)	05 Sep 2020 12:56:59
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:03:43

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Oct 2020 10:25:23
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Cynthia Montgomery (b) (4)	22 Oct 2020 20:34:04
User entered 'ug (ug)' reason for change: Data Entry Error	Cynthia Montgomery (b) (4)	22 Oct 2020 20:32:00
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:31:53
User entered 'mg (mg)'	Norma Barrientos (b) (4) (b) (4)	05 Sep 2020 12:56:59

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:56:59
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'once daily (QD)'	Norma Barrientos (b) (4)	05 Sep 2020 12:56:59

US3192575

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:56:59
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4)	05 Sep 2020 12:56:59

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:56:59
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered 'UN Jun 2020'	Norma Barrientos (b) (4)	05 Sep 2020 12:56:59
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered '0'	Norma Barrientos (b) (4)	05 Sep 2020 12:56:59
	(b) (4)	



**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	05 Sep 2020 12:56:59
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:56:59
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered 'No (N)'	Norma Barrientos (b) (4)	05 Sep 2020 12:56:59
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 12:56:59

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 12:56:59

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Aug 2021 22:03:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 12:56:59

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:43

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	07 Apr 2021 17:05:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 17:05:42
Data point term sent to Coder	System	07 Apr 2021 17:04:48
Coding entries removed.	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:04:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 21:57:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 21:57:36
Data point term sent to Coder	System	05 Sep 2020 12:57:55
User entered 'MAGNESIUM OXIDE'	Norma Barrientos (b) (4) (b) (4)	05 Sep 2020 12:57:40

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:43

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF (MH# 1 Tension Headaches). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 06:58:46
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF (MH# 1 Tension Headaches). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.	Damaris Atondo (b) (4) (b) (4)	13 Mar 2021 00:23:59
' answered with 'updated' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error	Damaris Atondo (b) (4) (b) (4)	13 Mar 2021 00:23:53
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF (MH# 1 Tension Headaches). Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification. (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 18:15:31
User closed query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' (Site from DM).		01 Feb 2021 16:50:00
Query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' answered with 'UPDATED FIELD.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	27 Jan 2021 01:49:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Mata (b) (4) (b) (4)	27 Jan 2021 01:49:52
User opened query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 08:55:10

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**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Cynthia Montgomery (b) (4)	22 Oct 2020 20:35:07
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	(b) (4) 05 Sep 2020 12:57:40

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:43

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR-RQ: Response noted. However, Indication reflects term "Prevention". Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 07:03:39
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
Query 'Per DM CLR-RQ: Response noted. However, Indication reflects term "Prevention". Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' answered with 'updated to reflect MH' (Site from DM).	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:04:36
User entered 'tension headaches' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:04:28
User opened query 'Per DM CLR-RQ: Response noted. However, Indication reflects term "Prevention". Please review if this indication should be changed to MH as there is an MH recorded that matches this medication and used within the same timeframe. If yes, please update indication as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 10:29:31
User closed query 'Per DM CLR: Prophylaxis = YES Inidcation = HEADACHE PREVENTION, however, there is a corresponding MedHistory condition that matches the ConMed's indication. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).		27 Oct 2020 10:38:25
Query 'Per DM CLR: Prophylaxis = YES; Inidcation = HEADACHE PREVENTION, however, there is a corresponding MedHistory condition that matches the ConMed's indication. Please confirm and update as appropriate, otherwise clarify.' answered with 'updated' (Site from DM).	Cynthia Montgomery (b) (4)	22 Oct 2020 20:35:15

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:03:43

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Prophylaxis = YES; Inidcation = HEADACHE PREVENTION, however, there is a corresponding MedHistory condition that matches the ConMed's indication. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 08:32:32
User entered 'HEADACHE PREVENTION'	Norma Barrientos (b) (4)	05 Sep 2020 12:57:40

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered '400'	Norma Barrientos (b) (4)	05 Sep 2020 12:57:40
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'mg (mg)'	Norma Barrientos (b) (4)	05 Sep 2020 12:57:40

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:57:40
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'once daily (QD)'	Norma Barrientos (b) (4)	05 Sep 2020 12:57:40

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:57:40
	(b) (4)	



**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Oral (ORAL)'	Norma Barrientos (b) (4)	05 Sep 2020 12:57:40

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:57:40
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'UN UNK 2015'	Norma Barrientos (b) (4)	05 Sep 2020 12:57:40

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered '0'	Norma Barrientos (b) (4)	05 Sep 2020 12:57:40
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered 'Yes (Y)'	Norma Barrientos (b) (4)	05 Sep 2020 12:57:40
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered empty.	Norma Barrientos (b) (4)	05 Sep 2020 12:57:40
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered 'No (N)'	Norma Barrientos (b) (4)	05 Sep 2020 12:57:40
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 12:57:40



**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 12:57:40

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Aug 2021 22:03:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 12:57:40

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:43

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 09:42:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 09:42:54
Data point term sent to Coder Coding entries removed.	System Damaris Atondo (b) (4)	13 Mar 2021 00:25:27 13 Mar 2021 00:24:36
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 06:05:35
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 06:05:35
Data point term sent to Coder User entered 'ibuprofen'	System maggie Tono (b) (4)	01 Oct 2020 01:02:40 01 Oct 2020 01:02:20

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	maggie Tono (b) (4)	01 Oct 2020 01:02:20

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
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 SORENESS AT THE INJECTION SITE FROM VACCINE 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 SORENESS AT THE INJECTION SITE FROM VACCINE did not meet the AE reporting criteria' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 06:23:05
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the SORENESS AT THE INJECTION SITE FROM VACCINE 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 SORENESS AT THE INJECTION SITE FROM VACCINE did not meet the AE reporting criteria' answered with 'updated' (Site from DM).	Damaris Atondo (b) (4)	13 Mar 2021 00:24:42
User entered 'SORENESS AT THE INJECTION SITE' reason for change: Data Entry Error	Damaris Atondo (b) (4)	13 Mar 2021 00:24:36

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:43

[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 SORENESS AT THE INJECTION SITE FROM VACCINE 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 SORENESS AT THE INJECTION SITE FROM VACCINE did not meet the AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 18:17:46
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 03:22:13
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' answered with 'INDICATION IS REPORTED IN DOSE DIARY 2. PLEASE REVISE.' (Site from DM).	Crystal Mata (b) (4)	27 Jan 2021 01:52:32
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:20:39
User entered 'soreness at the injection site from vaccine'	maggie Tono (b) (4)	01 Oct 2020 01:02:20

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '600'	maggie Tono (b) (4)	01 Oct 2020 01:02:20

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:43

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4)	01 Oct 2020 01:02:20



US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	maggie Tono (b) (4)	01 Oct 2020 01:02:20

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'once daily (QD)'	maggie Tono (b) (4)	01 Oct 2020 01:02:20

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:43

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	(b) (4) maggie Tono (b) (4)	01 Oct 2020 01:02:20

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:43

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Oral (ORAL)'	maggie Tono (b) (4)	01 Oct 2020 01:02:20

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	(b) (4) maggie Tono (b) (4)	01 Oct 2020 01:02:20

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '27 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Crystal Mata (b) (4)	27 Jan 2021 01:51:43
User entered 'un Sep 2020'	(b) (4)	
	maggie Tono (b) (4)	01 Oct 2020 01:02:20
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '0'	(b) (4) maggie Tono (b) (4)	01 Oct 2020 01:02:20

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	maggie Tono (b) (4)	01 Oct 2020 01:02:20



**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:03:43**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '27 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Crystal Mata (b) (4)	27 Jan 2021 01:51:43
User entered 'un Sep 2020'	(b) (4)	
	maggie Tono (b) (4)	01 Oct 2020 01:02:20
	(b) (4)	

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:03:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 06:23:16
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'updated' (Site from DM).	Damaris Atondo (b) (4) (b) (4)	13 Mar 2021 00:28:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Damaris Atondo (b) (4) (b) (4)	13 Mar 2021 00:28:25
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 18:18:18
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	01 Oct 2020 01:02:20

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User entered '1'	System	01 Oct 2020 01:02:20

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User entered '1'	System	01 Oct 2020 01:02:20

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Aug 2021 22:03:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:32:59
User entered '804 (804)'	System	01 Oct 2020 01:02:20

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User closed query 'Per MM: Please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (10 days after dose 2)' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 21:04:09
Query 'Per MM: Please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (10 days after dose 2)' answered with 'this is correct, PD will be filed ' (Site from DM).	Yvonne De Los Reyes (b) (4)	05 Jan 2021 01:24:15
User opened query 'Per MM: Please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (10 days after dose 2)' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 13:23:27
Query 'Per MM: Please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (8 days before dose 2)' canceled (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 13:23:12

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:43

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per MM: Please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. (8 days before dose 2)' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 13:10:45
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) (b) (4)	22 Oct 2020 20:32:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:32:39
Data point term sent to Coder	System	22 Oct 2020 20:32:13
User entered 'flu shot'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Yes (Y)'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23



**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'flu prevention'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '0.5'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'mL (mL)'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'once (ONCE)'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Intramuscular (INTRAMUSCULAR)'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:03:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23



**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '06 Oct 2020'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '0'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:03:43**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '06 Oct 2020'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	Cynthia Montgomery (b) (4)	22 Oct 2020 20:31:23

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User entered empty.	System	22 Oct 2020 20:31:23

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User entered empty.	System	22 Oct 2020 20:31:23

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Aug 2021 22:03:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:00
User entered empty.	System	22 Oct 2020 20:31:23



US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Feb 2021 21:44:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Feb 2021 21:44:35
Data point term sent to Coder	System	02 Feb 2021 16:32:11
User entered 'ibuprofen'	Saysamone Banks (b) (4) (b) (4)	02 Feb 2021 16:31:37

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:43

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	Saysamone Banks (b) (4)	02 Feb 2021 16:31:37

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:43

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review if reportable per protocol and be recorded in AE ecrf. Review and provide necessary updates as appropriate. Else, clarify. ' (Site from DM).		16 Apr 2021 18:59:37
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review if reportable per protocol and be recorded in AE ecrf. Review and provide necessary updates as appropriate. Else, clarify. ' answered with 'updated ' (Site from DM).	(b) (4) Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:07:15
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review if reportable per protocol and be recorded in AE ecrf. Review and provide necessary updates as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 09:41:25
User entered 'tenderness at injection site'	Saysamone Banks (b) (4)	02 Feb 2021 16:31:37
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '600'	Saysamone Banks (b) (4)	02 Feb 2021 16:31:37

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'mg (mg)'	Saysamone Banks (b) (4)	02 Feb 2021 16:31:37

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	02 Feb 2021 16:31:37
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'once (ONCE)'	(b) (4)	
	Saysamone Banks (b) (4)	02 Feb 2021 16:31:37
	(b) (4)	

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	02 Feb 2021 16:31:37
	(b) (4)	



**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Oral (ORAL)'	Saysamone Banks (b) (4)	02 Feb 2021 16:31:37

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:03:43**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Saysamone Banks (b) (4)	02 Feb 2021 16:31:37

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:43

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '22 Jan 2021'	(b) (4)	
	Saysamone Banks (b) (4)	02 Feb 2021 16:31:37
	(b) (4)	

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '0'	Saysamone Banks (b) (4)	02 Feb 2021 16:31:37

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	Saysamone Banks (b) (4)	02 Feb 2021 16:31:37

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:03:43**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '22 Jan 2021'	(b) (4)	
	Saysamone Banks (b) (4)	02 Feb 2021 16:31:37
	(b) (4)	

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:03:43

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of TENDERNESS AT INJECTION SITE in eDiary as it does not coincide with the treatment dates. Review if this is considered as UNSOLICITED event per protocol. If yes, please record this condition in AE eCRF and update this field response to "No". Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Mar 2021 07:00:51
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of TENDERNESS AT INJECTION SITE in eDiary as it does not coincide with the treatment dates. Review if this is considered as UNSOLICITED event per protocol. If yes, please record this condition in AE eCRF and update this field response to "No". Else, provide clarification. ' answered with 'updated' (Site from DM).	Damaris Atondo (b) (4) (b) (4)	13 Mar 2021 00:29:03
User entered 'No (N)' reason for change: Data Entry Error	Damaris Atondo (b) (4) (b) (4)	13 Mar 2021 00:28:57
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of TENDERNESS AT INJECTION SITE in eDiary as it does not coincide with the treatment dates. Review if this is considered as UNSOLICITED event per protocol. If yes, please record this condition in AE eCRF and update this field response to "No". Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 18:19:43
User entered 'Yes (Y)'	Saysamone Banks (b) (4) (b) (4)	02 Feb 2021 16:31:37

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User entered empty.	System	02 Feb 2021 16:31:37



**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User entered empty.	System	02 Feb 2021 16:31:37

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Aug 2021 22:03:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:02
User entered empty.	System	02 Feb 2021 16:31:37

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:03:43

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Mar 2021 00:32:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Mar 2021 00:32:55
Data point term sent to Coder	System	13 Mar 2021 00:31:30
User entered 'tylenol'	Damaris Atondo (b) (4) (b) (4)	13 Mar 2021 00:31:16

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	Damaris Atondo (b) (4)	13 Mar 2021 00:31:16

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'chills, body aches and headache'	Damaris Atondo (b) (4)	13 Mar 2021 00:31:16

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:03:43

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '500'	Damaris Atondo (b) (4)	13 Mar 2021 00:31:16

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'mg (mg)'	Damaris Atondo (b) (4)	13 Mar 2021 00:31:16

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:03:43

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Damaris Atondo (b) (4)	13 Mar 2021 00:31:16



**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'three times daily (TID)'	Damaris Atondo (b) (4)	13 Mar 2021 00:31:16

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:03:43

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Damaris Atondo (b) (4)	13 Mar 2021 00:31:16

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'Oral (ORAL)'	Damaris Atondo (b) (4)	13 Mar 2021 00:31:16

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:03:43

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered empty.	Damaris Atondo (b) (4)	13 Mar 2021 00:31:16

US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:03:43

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '24 Feb 2021'	Damaris Atondo (b) (4)	13 Mar 2021 00:31:16

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '0'	Damaris Atondo (b) (4)	13 Mar 2021 00:31:16

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered 'No (N)'	Damaris Atondo (b) (4)	13 Mar 2021 00:31:16

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:03:43**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
User entered '24 Feb 2021'	Damaris Atondo (b) (4)	13 Mar 2021 00:31:16



US3192575

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:03:43

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4 (occurred after 7 days post vaccination of BLINDED PHASE). Review and update entry as appropriate.' (Site from DM). User signature succeeded.	(b) (4)	13 Apr 2021 07:03:33
Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4 (occurred after 7 days post vaccination of BLINDED PHASE). Review and update entry as appropriate.' answered with 'updated' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error	John McGettigan (b) (4) (b) (4)	08 Apr 2021 01:17:41
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4 (occurred after 7 days post vaccination of BLINDED PHASE). Review and update entry as appropriate.' (Site from DM). User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:52
	Yvonne De Los Reyes (b) (4)	07 Apr 2021 17:08:46
	(b) (4), (b) (6)	31 Mar 2021 07:56:22
	Damaris Atondo (b) (4) (b) (4)	13 Mar 2021 00:31:16

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User entered '3'	System	13 Mar 2021 00:31:16

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User entered '1'	System	13 Mar 2021 00:31:16

**US3192575**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Aug 2021 22:03:43**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:33:05
User entered '804 (804)'	System	13 Mar 2021 00:31:16

US3192575

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 11 Aug 2021 22:03:43**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:17:41
	(b) (4)	
User entered 'No (N)'	Norma Barrientos (b) (4)	27 Sep 2020 18:35:50
	(b) (4)	