

US3172224 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:33:17

All time stamps listed in this document are displayed in GMT

US3172224

Form: Participant Creation

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

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Participant ID

US3172224

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

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US3172224

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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Was this visit performed? Yes   
No

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Visit date (dd MMM yyyy) 19 AUG 2020

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

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Folder OID SCRN

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US3172224

Folder: Screening

Form: Demographics

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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

US3172224

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 17 Feb 2021 13:11:38

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Date of Informed Consent (*dd MMM yyyy*) 19 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version  
Amendment 1   
Amendment 2   
Amendment 3   
Amendment 4   
Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail  
Withdrew Consent   
Inclusion/Exclusion   
Cohort Full   
Other

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously? Yes   
No

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3172224

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 17 Feb 2021 13:11:38

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Did the participant meet all eligibility criteria?

Yes

No

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US3172224

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 17 Feb 2021 13:11:38

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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) 17 Feb 2021 13:11:38

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

US3172224

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Condition	HEARTBURN
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: Medical History (3)

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Condition	LEFT KIDNEY STONES
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3172224

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Condition	RIGHT ELBOW FRACTURE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

US3172224

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:11:38

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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> )	19 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:55 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 13:55
Height ( <i>xxx.x</i> )	173.3 cm
Weight ( <i>xxx.x</i> )	72.2 kg
BMI ( <i>xxx.x</i> )	24.04031 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) 17 Feb 2021 13:11:38

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Was the physical examination performed?

Yes

No

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Date of examination (*dd MMM yyyy*) \_\_\_\_\_

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 17 Feb 2021 13:11:38

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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

**Specify**

**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) 17 Feb 2021 13:11:38

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 19 AUG 2020

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

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Folder OID VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 17 Feb 2021 13:11:38

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

What was the participant's randomization number? 106115

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

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

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

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

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

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

Liver Disease Yes  No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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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) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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 ( <i>dd MMM yyyy</i> )	19 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	13:55 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 13:55
Temperature ( <i>xxx.x</i> )	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	84 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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 ( <i>dd MMM yyyy</i> )	19 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	17:11 (24 HR)
Vital Signs Date and Time (derived)	19 AUG 2020 17:11
Temperature ( <i>xxx.x</i> )	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	74 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

19 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

Was study treatment given? Yes   
No

If No, reason not given

Participant declined due to Adverse Event

Physician withheld dose due to Adverse Event

Death

Lost To Follow-Up

Physician Decision

Pregnancy

Protocol Deviation

Study Terminated by Sponsor

Withdrawal of Consent by Participant

Confirmed COVID-19

Other

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 16:41 (24 HR)

Treatment Date and Time (derived) 19 AUG 2020 16:41

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) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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Was the sample collected? Yes  No

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Collection date (*dd MMM yyyy*) 19 AUG 2020

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Collection time (*00:00-23:59*) 16:06 (24 HR)

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Collection date and time (derived) 19 AUG 2020 16:06

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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Collection date ( <i>dd MMM yyyy</i> )			19 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:02	19 AUG 2020 16:02
Nasopharyngeal Swab 2	No		

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US3172224

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**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 19 AUG 2020 17:28

PC Open Date & Time 19 AUG 2020 17:01

PC Close Date & Time 19 AUG 2020 19:31

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**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 99.0 °F

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

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

PC Time Stamp	19 AUG 2020 20:27
PC Open Date & Time	19 AUG 2020 20:26
PC Close Date & Time	20 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 98.8 °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):

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

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

PC Time Stamp 20 AUG 2020 14:24

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

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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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.3 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	21 AUG 2020 14:14
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	22 AUG 2020 14:23
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**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	97.9 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 AUG 2020 15:40
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	24 AUG 2020 14:47
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.4 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	25 AUG 2020 18:06
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

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

Please record - **PAIN AT INJECTION SITE.**  
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with activity
- Any use of prescription pain  
reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

Please record - **UNDERARM GLAND SWELLING OR  
TENDERNESS.**  
Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter  
pain reliever > 24 hours or  
interferes with some activity
- Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp	19 AUG 2020 17:29
PC Open Date & Time	19 AUG 2020 17:01
PC Close Date & Time	19 AUG 2020 19:31

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

19 AUG 2020 20:28

PC Open Date & Time

19 AUG 2020 20:26

PC Close Date & Time

20 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 2

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	20 AUG 2020 14:24
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 3

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	21 AUG 2020 14:14
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 4

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

22 AUG 2020 14:24

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 5

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	23 AUG 2020 15:41
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 6

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

24 AUG 2020 14:47

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 7

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

25 AUG 2020 18:06

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

No

Yes

---

PC Time stamp	19 AUG 2020 17:29
PC Open Date & Time	19 AUG 2020 17:01
PC Close Date & Time	19 AUG 2020 19:31

---

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

No

Yes

---

PC Time stamp	19 AUG 2020 20:27
PC Open Date & Time	19 AUG 2020 20:26
PC Close Date & Time	20 AUG 2020 11:59

---

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

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	Yes <input type="checkbox"/>
PC Time stamp	20 AUG 2020 14:25
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

---

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

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	Yes <input type="checkbox"/>
PC Time stamp	21 AUG 2020 14:15
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

---

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

---

	Yes <input type="checkbox"/>
PC Time stamp	22 AUG 2020 14:24
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

---

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

---

	Yes <input type="checkbox"/>
PC Time stamp	23 AUG 2020 15:41
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

---

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

---

	Yes <input type="checkbox"/>
PC Time stamp	24 AUG 2020 14:48
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

---

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

---

	Yes <input type="checkbox"/>
PC Time stamp	25 AUG 2020 18:06
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

---

US3172224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 AUG 2020

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3172224

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes   
No

Date of Contact or Contact Attempt (dd MMM yyyy) 02 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3172224

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 09 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3172224

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 16 SEP 2020

---

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

---

Folder OID VISIT2

---

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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 ( <i>dd MMM yyyy</i> )	16 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	14:25 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 14:25
Temperature ( <i>xxx.x</i> )	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	95 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	91 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	75 mmHg
Diastolic Blood Pressure units	MMHG

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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 ( <i>dd MMM yyyy</i> )	16 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	15:58 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 15:58
Temperature ( <i>xxx.x</i> )	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	91 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	76 mmHg
Diastolic Blood Pressure units	MMHG

US3172224

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

16 SEP 2020

---

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

---

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 15:28 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 15:28

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

US3172224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

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Was the sample collected? Yes   
No

---

Collection date (*dd MMM yyyy*) 16 SEP 2020

---

Collection time (*00:00-23:59*) 15:17 (24 HR)

---

Collection date and time (derived) 16 SEP 2020 15:17

---

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Collection date ( <i>dd MMM yyyy</i> )			16 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:13	16 SEP 2020 15:13
Nasopharyngeal Swab 2	Yes	15:13	16 SEP 2020 15:13

---

US3172224

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**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 98.9 °F

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

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

PC Time Stamp 16 SEP 2020 15:58

PC Open Date & Time 16 SEP 2020 15:48

PC Close Date & Time 16 SEP 2020 18:18

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**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 16 SEP 2020 19:34  
PC Open Date & Time 16 SEP 2020 19:13  
PC Close Date & Time 17 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 SEP 2020 12:03
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

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

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

PC Time Stamp	18 SEP 2020 12:08
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 SEP 2020 16:33
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**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	98.4 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 SEP 2020 12:06
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	21 SEP 2020 12:51
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.8 °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):

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

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

PC Time Stamp 22 SEP 2020 15:53

PC Open Date & Time 22 SEP 2020 12:00

PC Close Date & Time 23 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 8

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 in °F</b>	97.6 °F
Was any <b>MEDICATION TAKEN today for pain or fever?</b>	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	23 SEP 2020 12:34
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**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	16 SEP 2020 15:58
PC Open Date & Time	16 SEP 2020 15:48
PC Close Date & Time	16 SEP 2020 18:18

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**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

16 SEP 2020 19:34

PC Open Date & Time

16 SEP 2020 19:13

PC Close Date & Time

17 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 2

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	17 SEP 2020 12:03
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 3

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

- Yes
- No

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp	18 SEP 2020 12:08
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 4

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

19 SEP 2020 16:34

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 5

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	20 SEP 2020 12:07
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**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

21 SEP 2020 12:51

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 7

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

22 SEP 2020 15:53

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

No

Yes

---

PC Time stamp	16 SEP 2020 15:58
PC Open Date & Time	16 SEP 2020 15:48
PC Close Date & Time	16 SEP 2020 18:18

---

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

No   
Yes

---

PC Time stamp	16 SEP 2020 19:34
PC Open Date & Time	16 SEP 2020 19:13
PC Close Date & Time	17 SEP 2020 11:59

---

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

---

	Yes <input type="checkbox"/>
PC Time stamp	17 SEP 2020 12:03
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

---

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

---

	Yes <input type="checkbox"/>
PC Time stamp	18 SEP 2020 12:08
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

---

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

---

	Yes <input type="checkbox"/>
PC Time stamp	19 SEP 2020 16:34
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

---

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

---

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

---

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

---

	Yes <input type="checkbox"/>
PC Time stamp	21 SEP 2020 12:52
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

---

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

---

	Yes <input type="checkbox"/>
PC Time stamp	22 SEP 2020 15:53
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

---

US3172224

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:33:17

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 SEP 2020 12:34
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3172224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 23 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3172224

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 30 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3172224

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 07 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3172224

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:11:47

Generated On: 09 Jun 2021 15:33:17

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 14 OCT 2020

---

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

---

Folder OID VISIT3

---

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 17 Feb 2021 13:11:47

Generated On: 09 Jun 2021 15:33:17

Were vital signs assessed? Yes   
No

Date of assessment (dd MMM yyyy) 14 OCT 2020

Time of assessment (00:00-23:59) 14:19 (24 HR)

Vital Signs Date and Time (derived) 14 OCT 2020 14:19

Temperature (xxx.x) 36.9 C

Route of measurement Oral   
Axillary   
Other

If Other, specify \_\_\_\_\_

Pulse (xxx) 92 beats/min

Pulse units BPM

Respiratory Rate (xxx) 18 breaths/min

Respiratory Rate units BREATHS/MIN

Systolic Blood Pressure (xxx) 116 mmHg

Systolic Blood Pressure units MMHG

Diastolic Blood Pressure (xxx) 79 mmHg

Diastolic Blood Pressure units MMHG

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3172224

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

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.*

---

US3172224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 14 OCT 2020

---

Collection time (*00:00-23:59*) 14:41 (24 HR)

---

Collection date and time (derived) 14 OCT 2020 14:41

---

US3172224

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 <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 OCT 2020 06:07:59
Patient Cloud Open Date & Time	19 OCT 2020 00:01
Patient Cloud Close Date & Time	23 OCT 2020 23:59

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 OCT 2020 05:57:15
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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 02 NOV 2020 06:06:18

Patient Cloud Open Date & Time 02 NOV 2020 00:01

Patient Cloud Close Date & Time 06 NOV 2020 23:59

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 NOV 2020 06:20:50
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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	23 NOV 2020 06:03:48
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 103

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

No

Yes

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

No

Yes

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

Date and time of submission 27 NOV 2020 01:37:28

Patient Cloud Open Date & Time 27 NOV 2020 00:01

Patient Cloud Close Date & Time 01 DEC 2020 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 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 DEC 2020 07:56:59
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 DEC 2020 05:55:59
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 DEC 2020 05:52:57
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 131

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

No

Yes

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

No

Yes

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

Date and time of submission 25 DEC 2020 08:59:40

Patient Cloud Open Date & Time 25 DEC 2020 00:01

Patient Cloud Close Date & Time 29 DEC 2020 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 138

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

No   
Yes

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

No   
Yes

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

Date and time of submission	01 JAN 2021 00:15:29
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	08 JAN 2021 05:53:48
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 06:07:35
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	22 JAN 2021 05:53:41
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	29 JAN 2021 09:24:20
Patient Cloud Open Date & Time	29 JAN 2021 00:01
Patient Cloud Close Date & Time	02 FEB 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 173

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

No

Yes

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

No

Yes

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

Date and time of submission 05 FEB 2021 06:30:53

Patient Cloud Open Date & Time 05 FEB 2021 00:01

Patient Cloud Close Date & Time 09 FEB 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 <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 FEB 2021 06:41:15
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 FEB 2021 12:00:25
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 194

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

No

Yes

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

No

Yes

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

Date and time of submission 26 FEB 2021 05:30:22

Patient Cloud Open Date & Time 26 FEB 2021 00:01

Patient Cloud Close Date & Time 02 MAR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 201

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

No

Yes

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

No

Yes

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

Date and time of submission 05 MAR 2021 06:07:40

Patient Cloud Open Date & Time 05 MAR 2021 00:01

Patient Cloud Close Date & Time 09 MAR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 <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 MAR 2021 05:45:46
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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

19 MAR 2021 05:28:12

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 222

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

No

Yes

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

No

Yes

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

Date and time of submission 26 MAR 2021 06:39:49

Patient Cloud Open Date & Time 26 MAR 2021 00:01

Patient Cloud Close Date & Time 30 MAR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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	02 APR 2021 06:28:30
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 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	09 APR 2021 06:08:51
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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 16 APR 2021 06:02:59

Patient Cloud Open Date & Time 16 APR 2021 00:01

Patient Cloud Close Date & Time 20 APR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 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	23 APR 2021 06:06:34
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 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	30 APR 2021 06:11:33
Patient Cloud Open Date & Time	30 APR 2021 00:01
Patient Cloud Close Date & Time	04 MAY 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 264

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

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

<a href="#">Patient Cloud Open Date &amp; Time</a>	14 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 MAY 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 278

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 285

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 JUN 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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18 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 313

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 JUN 2021 00:01
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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**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  Yes

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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02 JUL 2021 00:01

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06 JUL 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

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

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09 JUL 2021 00:01

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13 JUL 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

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**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

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

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Date and time of submission

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16 JUL 2021 00:01

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20 JUL 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**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   
Yes

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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23 JUL 2021 00:01

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27 JUL 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 348

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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03 AUG 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

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**TIMEPOINT**

DAY 355

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

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

Date and time of submission

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06 AUG 2021 00:01

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10 AUG 2021 23:59

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Folder: New Safety Follow Up Diary (1)

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**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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13 AUG 2021 00:01

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17 AUG 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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20 AUG 2021 00:01

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24 AUG 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

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

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

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27 AUG 2021 00:01

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31 AUG 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

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

**Form: Safety Follow Up Diary**

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Date and time of submission

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03 SEP 2021 00:01

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07 SEP 2021 23:59

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**TIMEPOINT**

DAY 390

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

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14 SEP 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

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21 SEP 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 404

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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Date and time of submission

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24 SEP 2021 00:01

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28 SEP 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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  Yes

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

Date and time of submission

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01 OCT 2021 00:01

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05 OCT 2021 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 418

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

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12 OCT 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 425

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

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**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 OCT 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 OCT 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 439

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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29 OCT 2021 00:01

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02 NOV 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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   
Yes

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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05 NOV 2021 00:01

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09 NOV 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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12 NOV 2021 00:01

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16 NOV 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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  Yes

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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19 NOV 2021 00:01

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23 NOV 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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Date and time of submission

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26 NOV 2021 00:01

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30 NOV 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 10 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 14 DEC 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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   
Yes

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 502

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 509

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 530

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 FEB 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#) 08 FEB 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 FEB 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 APR 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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   
Yes

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

US3172224

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

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**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 APR 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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   
Yes

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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22 APR 2022 00:01

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26 APR 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 621

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

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03 MAY 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 635

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 649

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

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31 MAY 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 656

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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03 JUN 2022 00:01

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07 JUN 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 670

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#) 28 JUN 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

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05 JUL 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 691

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 705

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

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**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

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26 JUL 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 712

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

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02 AUG 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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  Yes

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 12 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#) 16 AUG 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

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23 AUG 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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  Yes

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

09 SEP 2022 00:01

---

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

---

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 OCT 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 07 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#) 11 OCT 2022 23:59

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US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 789

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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

---

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

DAY 796

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3172224

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

21 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

---

US3172224

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:33:17

---

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		05 MAR 2021 06:07:50

---

US3172224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 12 NOV 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3172224

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:38

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 15 DEC 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3172224

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes   
No

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

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

Comments

*If Contact Not Made, please provide Comments*

US3172224

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes   
No

Date of Contact or Contact Attempt (dd MMM yyyy) 15 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3172224

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) \_\_\_\_\_

---

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

---

Folder OID VISIT4

---

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 16:25:35

Generated On: 09 Jun 2021 15:33:17

Were vital signs assessed? Yes   
No

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

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

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral   
Axillary   
Other

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3172224

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

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.*

---

US3172224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Was the sample collected? Yes   
No

Collection date (dd MMM yyyy) \_\_\_\_\_

Collection time (00:00-23:59) \_\_\_\_\_

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

US3172224

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 14 APR 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3172224

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

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* \_\_\_\_\_

US3172224

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3172224

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:33:17

---

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

---

US3172224

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:33:17

---

Generate Next COVID-19 Assessment

Yes

No

---

US3172224

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

Form: Visit Date

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 29 JAN 2021

---

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

---

Folder OID UNBLND\_DECIDE

---

US3172224

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Date of updated informed consent ( <i>dd MMM yyyy</i> )	06 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> )	29 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

US3172224

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

Height	ND - Not Done
Weight	079.7 kg
BMI (xxx.x)	

---

---

US3172224

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Height	ND - Not Done
Weight	079.7 kg
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 MAR 2021
Time of assessment (00:00-23:59)	13:10 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 13:10
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3172224

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Height	ND - Not Done
Weight	079.7 kg
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 MAR 2021
Time of assessment (00:00-23:59)	15:12 (24 HR)
Vital Signs Date and Time (derived)	19 MAR 2021 15:12
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3172224

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

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

19 MAR 2021

---

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

---

US3172224

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

Form: Exposure

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Was study treatment given? Yes   
No

If No, reason not given

Participant declined due to Adverse Event

Physician withheld dose due to Adverse Event

Death

Lost To Follow-Up

Physician Decision

Pregnancy

Protocol Deviation

Study Terminated by Sponsor

Withdrawal of Consent by Participant

Confirmed COVID-19

Other

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 19 MAR 2021

What was the treatment time? (00:00-23:59) 14:42 (24 HR)

Treatment Date and Time (derived) 19 MAR 2021 14:42

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

US3172224

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 29 JAN 2021

---

Collection time (*00:00-23:59*) 13:35 (24 HR)

---

Collection date and time (derived) 29 JAN 2021 13:35

---

US3172224

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 29 JAN 2021

---

Collection time (*00:00 - 23:59*) 13:36

---

Collection Date and Time (derived) 29 JAN 2021 13:36

---

US3172224

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

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 26 MAR 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3172224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

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

---

US3172224

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 13 APR 2021

---

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

---

Folder OID OLD29

---

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

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 ( <i>dd MMM yyyy</i> )	13 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	13:50 (24 HR)
Vital Signs Date and Time (derived)	13 APR 2021 13:50
Temperature ( <i>xxx.x</i> )	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	80 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 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> )	72 mmHg
Diastolic Blood Pressure units	MMHG

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

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 ( <i>dd MMM yyyy</i> )	13 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	15:23 (24 HR)
Vital Signs Date and Time (derived)	13 APR 2021 15:23
Temperature ( <i>xxx.x</i> )	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	60 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	78 mmHg
Diastolic Blood Pressure units	MMHG

US3172224

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

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.*

---

US3172224

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

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) 13 APR 2021

What was the treatment time? (00:00-23:59) 14:53 (24 HR)

Treatment Date and Time (derived) 13 APR 2021 14:53

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

US3172224

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Was Contact Attempted? Yes   
No

Date of Contact or Contact Attempt (dd MMM yyyy) 21 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3172224

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3172224

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) \_\_\_\_\_

---

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

---

Folder OID \_\_\_\_\_

US3172224

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	_____
Time of assessment ( <i>00:00-23:59</i> )	_____
Vital Signs Date and Time (derived)	_____
Temperature ( <i>xxx.x</i> )	_____
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	_____
Pulse units	_____
Respiratory Rate ( <i>xxx</i> )	_____
Respiratory Rate units	_____
Systolic Blood Pressure ( <i>xxx</i> )	_____
Systolic Blood Pressure units	_____
Diastolic Blood Pressure ( <i>xxx</i> )	_____
Diastolic Blood Pressure units	_____
Height (derived)	_____
Weight (derived)	_____

US3172224

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

---

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.*

---

US3172224

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Was the sample collected? Yes   
No

Collection date (*dd MMM yyyy*) \_\_\_\_\_

Collection time (*00:00-23:59*) \_\_\_\_\_

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

US3172224

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

AEID USA-US118-2021-MRNA-1273-P30  
1000004

Adverse event HEMOPNEUMOTHORAX -  
SECONDARY TO RIB CAGE  
MULTIPLE FRACTURES.

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 23 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) 27 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 True

Hospital Admission Date (dd MMM yyyy) 23 JAN 2021

Hospital Discharge Date (dd MMM yyyy) 27 JAN 2021

Admitted to ICU? Yes   
No   
Unknown

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EAB) (1725)

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

---

HEMOPNEUMOTHORAX  
SECONDARY TO RIGHT RIB  
CAGE MULTIPLE FRACTURES  
DUE TO A MOTOR VEHICLE  
ACCIDENT, REQUIRING  
HOSPITALIZATION AND  
THORACOTOMY. DISCHARGED  
HOME, STABLE AND  
RECOVERED FROM  
HEMOPNEUMOTHORAX  
(ACUTE / TRAUMATIC).

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

AEID USA-US118-2021-MRNA-1273-P30  
1000004

Adverse event RIGHT RIB CAGE MULTIPLE  
FRACTURES

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 23 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) 1 MAR 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 True

Hospital Admission Date (dd MMM yyyy) 23 JAN 2021

Hospital Discharge Date (dd MMM yyyy) 27 JAN 2021

Admitted to ICU? Yes   
No   
Unknown

Number of Days in ICU

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EAB) (1725)

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

---

RIGHT RIB CAGE MULTIPLE  
FRACTURES SECONDARY TO A  
MOTOR VEHICLE ACCIDENT  
ON 1/23/2021 REQUIRING  
HOSPITALIZATION DUE TO  
MULTIPLE TRAUMA AND  
HEMOPNEUMOTHORAX  
RESOLVED WITH  
THORACOSTOMY (CHEST  
TUBE) MULTIPLE ABRASIONS  
RIGHT KNEE, BOTH ELBOW,  
ABDOMEN, HIPS, AND  
FOREHEAD WITHOUT  
CLINICALLY SIGNIFICANCE. HE  
WAS DISCHARGED HOME ON  
1/27/2021 ON A STABLE  
CONDITION WITH ORAL MEDS  
FOR PAIN AND SWELLING.  
WILL MONITOR.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

AEID	
Adverse event	MULTIPLE SKIN ABRASIONS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	23 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)	03 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

---

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

Yes

No

---

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

---

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication IBUPROFEN

Prophylaxis Yes   
No

Indication BACK PAIN

Dose per administration 600

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

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 1995

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 19 AUG 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication FAMOTIDINE

Prophylaxis Yes   
No

Indication HEARTBURN

Dose per administration 10

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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EAB) (1725)

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US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

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 2010

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication IBUPROFEN

Prophylaxis Yes   
No

Indication HISTORICAL BACK PAIN

Dose per administration 600

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

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 1995

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 16 OCT 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication OXYCODONE

Prophylaxis Yes   
No

Indication RIGHT RIB CAGE PAIN

Dose per administration 10

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 6 HOURS

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

359 of 2066

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 23 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 27 JAN 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication TORADOL

Prophylaxis Yes   
No

Indication RIGHT RIB CAGE PAIN

Dose per administration 15

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

EVERY 6 HOURS

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

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 checked="" type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

Start date (*dd MMM yyyy*) 23 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (*dd MMM yyyy*) 27 JAN 2021

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication TOVENOX

Prophylaxis Yes   
No

Indication RIGHT RIB CAGE PAIN

Dose per administration 40

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 12 HOURS

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 23 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 27 JAN 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication GABAPENTIN

Prophylaxis Yes   
No

Indication RIGHT RIB CAGE PAIN

Dose per administration 300

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

EVERY 8 HOURS

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 23 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 15 MAR 2021

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication IBUPROFEN

Prophylaxis Yes   
No

Indication RIGHT RIB CAGE PAIN - FRACTURES

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

EVERY 6 HOURS

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

---

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (dd MMM yyyy) 23 JAN 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

Name of Medication TYLENOL

Prophylaxis Yes   
No

Indication RIGHT RIB CAGE PAIN -  
FRACTURES

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

EVERY 6 HOURS

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) 23 JAN 2021

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3172224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 17 Feb 2021 13:11:37

Generated On: 09 Jun 2021 15:33:17

---

Were any concomitant procedures performed?

Yes

No

---

**If yes, please complete Concomitant Procedures form.**

---

US3172224

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:33:17

---

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

---

US3172224

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:33:17

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

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

SAEID	USA-US118-2021-MRNA-1273-P30 1000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

SAEID	USA-US118-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	01/FEB/2021 13:13
<b>Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.</b>	<input checked="" type="checkbox"/> True

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 16:25:33

Generated On: 09 Jun 2021 15:33:17

SAEID	USA-US118-2021-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	08/APR/2021 10:29
<b>Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.</b>	<input checked="" type="checkbox"/> True

Audit

US3172224 (Prod: Suncoast Research Group LLC - ERN-PPDS)

US3172224

Form: Participant Creation

Generated On: 09 Jun 2021 15:33:17

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'US3172224'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 19:09:34

US3172224

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:08:33

US3172224

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 19:09:35

US3172224

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:08:33

US3172224

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'SCRN'	System	19 Aug 2020 21:08:33

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered (b) (6) 1970'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 19:09:36

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '50'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:28

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'YEARS'	System	19 Aug 2020 21:09:28

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '50'	System	19 Aug 2020 20:50:23

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Male (M)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:28

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:28

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '1'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:28

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:28

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:28

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:28

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:28

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:28

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:28

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:28

US3172224

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:33:17

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:28

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '19 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 20:50:23

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'Aug 2020'	System	19 Aug 2020 20:50:23

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '2020'	System	19 Aug 2020 20:50:23

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 18:59:10
User entered 'Amendment 2 (2)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 20:50:23

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 20:50:23

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 20:50:23

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 20:50:23

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 20:50:23

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 19:09:35

US3172224

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:33:17

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '1'	System	19 Aug 2020 20:50:28

US3172224

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 20:50:28

US3172224

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:33:17

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:13:06

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Hypermetropia, LLT: Hypermetropia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 22:23:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 22:23:11
Data point term sent to Coder	System	19 Aug 2020 21:14:11
User entered 'HYPERMETROPHIA'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:13:34

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'UN UNK 2000'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:13:34

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:13:34

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:13:34

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:13:34

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:13:34

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'Jan 2000'	System	19 Aug 2020 21:13:34

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '2000'	System	19 Aug 2020 21:13:34

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered empty.	System	19 Aug 2020 21:13:34

US3172224

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered empty.	System	19 Aug 2020 21:13:34

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:16:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:16:10
Data point term sent to Coder	System	19 Aug 2020 21:14:12
User entered 'HEARTBURN'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:13:54

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'UN UNK 2010'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:13:54

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:13:54

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:13:54

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:13:54

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:13:54

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'Jan 2010'	System	19 Aug 2020 21:13:54

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '2010'	System	19 Aug 2020 21:13:54

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered empty.	System	19 Aug 2020 21:13:54

US3172224

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered empty.	System	19 Aug 2020 21:13:54

US3172224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User closed query 'Per DM CLR: Please specify the location of KIDNEY STONES (e.g. right, left or both kidneys). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 22:58:03
User coded data point as SOC: Renal and urinary disorders, HLG: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:08:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:08:40
Query 'Per DM CLR: Please specify the location of KIDNEY STONES (e.g. right, left or both kidneys). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'Data updated. No recurrence, No surgery, no liotripsy, no other treatment stone not retrieved' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 22:41:10
Data point term sent to Coder	System	10 Sep 2020 22:40:08
Coding entries removed.	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 22:39:13
User entered 'Left KIDNEY STONES' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	10 Sep 2020 22:39:13
User opened query 'Per DM CLR: Please specify the location of KIDNEY STONES (e.g. right, left or both kidneys). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	05 Sep 2020 14:35:08
User coded data point as SOC: Renal and urinary disorders, HLG: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:16:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:16:10

US3172224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	19 Aug 2020 21:15:12
User entered 'KIDNEY STONES'	Mariete Rendon (b) (4)	19 Aug 2020 21:14:19
	(b) (4)	

US3172224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:14:19

US3172224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:14:19

US3172224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:14:19

US3172224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:14:19

US3172224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:14:19

US3172224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'Jan 2015'	System	19 Aug 2020 21:14:19

US3172224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '2015'	System	19 Aug 2020 21:14:19

US3172224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'Jan 2015'	System	19 Aug 2020 21:14:19

US3172224

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '2015'	System	19 Aug 2020 21:14:19

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User coded data point as SOC: Injury, poisoning and procedural complications, HLGTT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Upper limb fracture, LLT: Elbow fracture - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:16:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:16:11
Data point term sent to Coder	System	19 Aug 2020 21:15:14
User entered 'RIGHT ELBOW FRACTURE'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:14:40

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:14:40

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:14:40

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:14:40

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:14:40

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:14:40

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'Jan 2015'	System	19 Aug 2020 21:14:40

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '2015'	System	19 Aug 2020 21:14:40

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'Jan 2015'	System	19 Aug 2020 21:14:40

US3172224

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '2015'	System	19 Aug 2020 21:14:40

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLG: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:16:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:16:11
Data point term sent to Coder	System	19 Aug 2020 21:15:15
User entered 'BACK PAIN'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:04

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'UN UNK 1995'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:04

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:04

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:04

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:04

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:04

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'Jan 1995'	System	19 Aug 2020 21:15:04

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '1995'	System	19 Aug 2020 21:15:04

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered empty.	System	19 Aug 2020 21:15:04

US3172224

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered empty.	System	19 Aug 2020 21:15:04

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '19 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '13:55'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '19 Aug 2020 13:55'	System	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '173.3' cm	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:05
DataPoint set to visible.	System	19 Aug 2020 20:50:28

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '72.2' kg	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:05
DataPoint set to visible.	System	19 Aug 2020 20:50:28

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
Amendment Manager: User entered '24.04031'	System	17 Sep 2020 00:14:47
User entered '24.0'	System	19 Aug 2020 21:10:05
DataPoint set to visible.	System	19 Aug 2020 20:50:28

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'kg/m2'	System	19 Aug 2020 21:10:05
DataPoint set to visible.	System	19 Aug 2020 20:50:28

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 04:53:32
Query 'Data is required. Please provide.' answered with 'Not Done.' (Site from System).	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 15:33:55
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 21:10:05
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'bpm'	System	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'breaths/min'	System	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'mmHg'	System	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'mmHg'	System	19 Aug 2020 21:10:05

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53

US3172224

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53

US3172224

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Sep 2020 21:30:31
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:21

US3172224

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User closed query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	28 Sep 2020 21:30:31
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Sep 2020 21:30:31
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 19:40:08
User entered '19 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:21

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

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 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

[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 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

**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 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

**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 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

[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 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

[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 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

**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 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

[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 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

[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 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

**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 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

**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 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

**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 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

[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 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

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 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '1'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:33:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:09:12

US3172224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:33

US3172224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '19 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:33

US3172224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:10:33

US3172224

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'VISIT1'	System	19 Aug 2020 21:10:33

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '19 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 19:14:14

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:41:07
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:41:07
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Aug 2020 19:14:14
User entered '106115' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 19:14:14

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	19 Aug 2020 19:14:14

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:49

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:49

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:49

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:49

US3172224

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:33:17

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:49

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '19 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '13:55'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '19 Aug 2020 13:55'	System	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '37.1' C	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '84'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'bpm'	System	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '16'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'breaths/min'	System	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '114'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'mmHg'	System	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '85'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'mmHg'	System	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 12:57:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 12:57:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 12:57:48
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 21:11:04
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '19 Aug 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 12:57:48
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:41:05
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	20 Aug 2020 12:57:48
User entered '17:11' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 12:57:48
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '19 Aug 2020 17:11'	System	20 Aug 2020 12:57:48
User entered empty.	System	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '36.6' C reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 12:57:48
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 12:57:48
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '74' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 12:57:48
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'bpm'	System	20 Aug 2020 12:57:48
User entered empty.	System	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '14' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 12:57:48
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'breaths/min'	System	20 Aug 2020 12:57:48
User entered empty.	System	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '119' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 12:57:48
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'mmHg'	System	20 Aug 2020 12:57:48
User entered empty.	System	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '78' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Aug 2020 12:57:48
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'mmHg'	System	20 Aug 2020 12:57:48
User entered empty.	System	19 Aug 2020 21:11:04

US3172224

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Sep 2020 21:30:45
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:26

US3172224

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '19 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	28 Sep 2020 21:30:45
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:11:26

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 20:51:16

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 20:51:16

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 20:51:16

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'MRNA-1273 OR PLACEBO'	System	19 Aug 2020 20:51:16

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '19 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 20:51:16

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '16:41'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 20:51:16

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '19 Aug 2020 16:41'	System	19 Aug 2020 20:51:16

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Right Arm (RIGHT ARM)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 20:51:16

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'ONCE'	System	19 Aug 2020 20:51:16

US3172224

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'INTRAMUSCULAR'	System	19 Aug 2020 20:51:16

US3172224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:17:03

US3172224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '19 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:17:03

US3172224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '16:06'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:17:03

US3172224

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '19 Aug 2020 16:06'	System	19 Aug 2020 21:17:03

US3172224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:33:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '19 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:17:16

US3172224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:17:16

US3172224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:17:16

US3172224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '16:02'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:17:16

US3172224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '19 Aug 2020 16:02'	System	19 Aug 2020 21:17:16

US3172224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:17:16

US3172224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 14:24:18
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:17:16

US3172224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 14:24:18
User entered '16:02'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:17:16

US3172224

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered empty.	System	17 Sep 2020 14:24:18
User entered '19 Aug 2020 16:02'	System	19 Aug 2020 21:17:16

US3172224

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 16:22:58

US3172224

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '1'	System	31 Aug 2020 16:22:58

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:28:43', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c8c86128-7851-43ab-8fd0-72ccfe8f2a08'	System	19 Aug 2020 21:29:04
User entered 'Yes (Y)'	System	19 Aug 2020 21:29:04

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:28:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c8c86128-7851-43ab-8fd0-72ccfe8f2a08' User entered '98.3'	System	19 Aug 2020 21:29:04
	System	19 Aug 2020 21:29:04

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:28:54', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c8c86128-7851-43ab-8fd0-72ccfe8f2a08'	System	19 Aug 2020 21:29:04
User entered 'No (N)'	System	19 Aug 2020 21:29:04

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:28:59', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c8c86128-7851-43ab-8fd0-72ccfe8f2a08' User entered '19 Aug 2020 17:28'	System	19 Aug 2020 21:29:04
	System	19 Aug 2020 21:29:04

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Aug 2020 17:01'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Aug 2020 19:31'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:26:51', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3774af98-6797-45a3-b40a-fc290d313219' User entered 'Yes (Y)'	System	20 Aug 2020 00:27:14
	System	20 Aug 2020 00:27:14

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:03', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3774af98-6797-45a3-b40a-fc290d313219' User entered '99.0'	System	20 Aug 2020 00:27:14
	System	20 Aug 2020 00:27:14

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3774af98-6797-45a3-b40a-fc290d313219' User entered 'No (N)'	System	20 Aug 2020 00:27:14
	System	20 Aug 2020 00:27:14

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:12', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3774af98-6797-45a3-b40a-fc290d313219' User entered '19 Aug 2020 20:27'	System	20 Aug 2020 00:27:14
	System	20 Aug 2020 00:27:14

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Aug 2020 20:26'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 2'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:23:42', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1435759d-d40b-4779-9344-2f508e9c92e9' User entered 'Yes (Y)'	System	20 Aug 2020 18:24:24
	System	20 Aug 2020 18:24:24

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:23:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1435759d-d40b-4779-9344-2f508e9c92e9' User entered '98.8'	System	20 Aug 2020 18:24:24
	System	20 Aug 2020 18:24:24

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:01', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1435759d-d40b-4779-9344-2f508e9c92e9' User entered 'Yes (Y)'	System	20 Aug 2020 18:24:24
	System	20 Aug 2020 18:24:24

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
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 'subject denies taking any new medication' (Site from System).	Ipsita Abalokita (b) (4) (b) (4)	08 Sep 2020 12:36:00
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).	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 21:05:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1435759d-d40b-4779-9344-2f508e9c92e9'	System	20 Aug 2020 18:24:24
User entered '1'	System	20 Aug 2020 18:24:24

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1435759d-d40b-4779-9344-2f508e9c92e9' User entered '0'	System	20 Aug 2020 18:24:24
	System	20 Aug 2020 18:24:24

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:22', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1435759d-d40b-4779-9344-2f508e9c92e9' User entered '20 Aug 2020 14:24'	System	20 Aug 2020 18:24:24
	System	20 Aug 2020 18:24:24

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 3'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:41', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3598cb7c-ab8e-45c3-94fd-e76dc63476f8' User entered 'Yes (Y)'	System	21 Aug 2020 18:14:56
	System	21 Aug 2020 18:14:56

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:47', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3598cb7c-ab8e-45c3-94fd-e76dc63476f8' User entered '98.3'	System	21 Aug 2020 18:14:56
	System	21 Aug 2020 18:14:56

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:49', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3598cb7c-ab8e-45c3-94fd-e76dc63476f8' User entered 'No (N)'	System	21 Aug 2020 18:14:56
	System	21 Aug 2020 18:14:56

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3598cb7c-ab8e-45c3-94fd-e76dc63476f8' User entered '21 Aug 2020 14:14'	System	21 Aug 2020 18:14:56
	System	21 Aug 2020 18:14:56

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 4'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:23:28', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '955aea00-3f21-4dd1-8fc8-0f9d37b58046' User entered 'Yes (Y)'	System	22 Aug 2020 18:23:55
	System	22 Aug 2020 18:23:55

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:23:37', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '955aea00-3f21-4dd1-8fc8-0f9d37b58046' User entered '98.8'	System	22 Aug 2020 18:23:55
	System	22 Aug 2020 18:23:55

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:23:41', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '955aea00-3f21-4dd1-8fc8-0f9d37b58046'	System	22 Aug 2020 18:23:55
User entered 'No (N)'	System	22 Aug 2020 18:23:55

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:23:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '955aea00-3f21-4dd1-8fc8-0f9d37b58046' User entered '22 Aug 2020 14:23'	System	22 Aug 2020 18:23:55
	System	22 Aug 2020 18:23:55

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 5'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:30', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3e65f33d-2767-4cd2-b876-db9021b9000e' User entered 'Yes (Y)'	System	23 Aug 2020 19:40:48
	System	23 Aug 2020 19:40:48

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:37', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3e65f33d-2767-4cd2-b876-db9021b9000e' User entered '97.9'	System	23 Aug 2020 19:40:48
	System	23 Aug 2020 19:40:48

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:40', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3e65f33d-2767-4cd2-b876-db9021b9000e' User entered 'No (N)'	System	23 Aug 2020 19:40:48
	System	23 Aug 2020 19:40:48

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:43', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3e65f33d-2767-4cd2-b876-db9021b9000e' User entered '23 Aug 2020 15:40'	System	23 Aug 2020 19:40:48
	System	23 Aug 2020 19:40:48

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 6'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:24', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '78939004-b03b-4e7d-bf9a-8e812bc99208' User entered 'Yes (Y)'	System	24 Aug 2020 18:47:41
	System	24 Aug 2020 18:47:41

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '78939004-b03b-4e7d-bf9a-8e812bc99208' User entered '98.8'	System	24 Aug 2020 18:47:41
	System	24 Aug 2020 18:47:41

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:32', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '78939004-b03b-4e7d-bf9a-8e812bc99208' User entered 'No (N)'	System	24 Aug 2020 18:47:41
	System	24 Aug 2020 18:47:41

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:34', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '78939004-b03b-4e7d-bf9a-8e812bc99208' User entered '24 Aug 2020 14:47'	System	24 Aug 2020 18:47:41
	System	24 Aug 2020 18:47:41

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 7'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:06', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7f261fd2-3b19-4e71-bfbe-46cfa897c10' User entered 'Yes (Y)'	System	25 Aug 2020 22:06:26
	System	25 Aug 2020 22:06:26

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:18', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7f261fd2-3b19-4e71-bfbe-46cfa897c10' User entered '98.4'	System	25 Aug 2020 22:06:26
	System	25 Aug 2020 22:06:26

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7f261fd2-3b19-4e71-bfbe-46cfa897c10'	System	25 Aug 2020 22:06:26
User entered 'No (N)'	System	25 Aug 2020 22:06:26

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:23', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7f261fd2-3b19-4e71-bfbe-46cfa897c10' User entered '25 Aug 2020 18:06'	System	25 Aug 2020 22:06:26
	System	25 Aug 2020 22:06:26

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:06', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '59f2e3eb-ffa5-4327-ac52-04ca036ef57a'	System	19 Aug 2020 21:29:37
User entered 'None (1)'	System	19 Aug 2020 21:29:37

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:09', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '59f2e3eb-ffa5-4327-ac52-04ca036ef57a' User entered 'No (N)'	System	19 Aug 2020 21:29:37
	System	19 Aug 2020 21:29:37

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '59f2e3eb-ffa5-4327-ac52-04ca036ef57a' User entered 'No (N)'	System	19 Aug 2020 21:29:37
	System	19 Aug 2020 21:29:37

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:30', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '59f2e3eb-ffa5-4327-ac52-04ca036ef57a'	System	19 Aug 2020 21:29:37
User entered 'None (1)'	System	19 Aug 2020 21:29:37

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:35', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '59f2e3eb-ffa5-4327-ac52-04ca036ef57a' User entered '19 Aug 2020 17:29'	System	19 Aug 2020 21:29:37
	System	19 Aug 2020 21:29:37

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Aug 2020 17:01'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Aug 2020 19:31'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:51', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '258b9e05-1fd0-45b6-badf-3326d6dc75eb' User entered 'None (1)'	System	20 Aug 2020 00:28:07
	System	20 Aug 2020 00:28:07

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:54', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '258b9e05-1fd0-45b6-badf-3326d6dc75eb' User entered 'No (N)'	System	20 Aug 2020 00:28:07
	System	20 Aug 2020 00:28:07

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '258b9e05-1fd0-45b6-badf-3326d6dc75eb' User entered 'No (N)'	System	20 Aug 2020 00:28:07
	System	20 Aug 2020 00:28:07

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:28:02', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '258b9e05-1fd0-45b6-badf-3326d6dc75eb' User entered 'None (1)'	System	20 Aug 2020 00:28:07
	System	20 Aug 2020 00:28:07

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:28:04', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '258b9e05-1fd0-45b6-badf-3326d6dc75eb' User entered '19 Aug 2020 20:28'	System	20 Aug 2020 00:28:07
	System	20 Aug 2020 00:28:07

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Aug 2020 20:26'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 2'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:27', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f3722669-a959-41d2-b2d0-d421465141d1' User entered 'None (1)'	System	20 Aug 2020 18:24:43
	System	20 Aug 2020 18:24:43

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:30', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f3722669-a959-41d2-b2d0-d421465141d1' User entered 'No (N)'	System	20 Aug 2020 18:24:43
	System	20 Aug 2020 18:24:43

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:33', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f3722669-a959-41d2-b2d0-d421465141d1' User entered 'No (N)'	System	20 Aug 2020 18:24:43
	System	20 Aug 2020 18:24:43

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:37', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f3722669-a959-41d2-b2d0-d421465141d1' User entered 'None (1)'	System	20 Aug 2020 18:24:43
	System	20 Aug 2020 18:24:43

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:40', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f3722669-a959-41d2-b2d0-d421465141d1' User entered '20 Aug 2020 14:24'	System	20 Aug 2020 18:24:43
	System	20 Aug 2020 18:24:43

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 3'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '074fad62-257e-45a6-8204-c1a19eeaf167'	System	21 Aug 2020 18:14:36
User entered 'None (1)'	System	21 Aug 2020 18:14:36

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:22', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '074fad62-257e-45a6-8204-c1a19eeaf167'	System	21 Aug 2020 18:14:36
User entered 'No (N)'	System	21 Aug 2020 18:14:36

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:26', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '074fad62-257e-45a6-8204-c1a19eeaf167'	System	21 Aug 2020 18:14:36
User entered 'No (N)'	System	21 Aug 2020 18:14:36

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '074fad62-257e-45a6-8204-c1a19eeaf167'	System	21 Aug 2020 18:14:36
User entered 'None (1)'	System	21 Aug 2020 18:14:36

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:35', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '074fad62-257e-45a6-8204-c1a19eeaf167' User entered '21 Aug 2020 14:14'	System	21 Aug 2020 18:14:36
	System	21 Aug 2020 18:14:36

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 4'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:23:58', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'de2ddd4c-e8cf-47bb-98ef-12cb88f2729e' User entered 'None (1)'	System	22 Aug 2020 18:24:18
	System	22 Aug 2020 18:24:18

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:04', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'de2ddd4c-e8cf-47bb-98ef-12cb88f2729e' User entered 'No (N)'	System	22 Aug 2020 18:24:18
	System	22 Aug 2020 18:24:18

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'de2ddd4c-e8cf-47bb-98ef-12cb88f2729e' User entered 'No (N)'	System	22 Aug 2020 18:24:18
	System	22 Aug 2020 18:24:18

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'de2ddd4c-e8cf-47bb-98ef-12cb88f2729e' User entered 'None (1)'	System	22 Aug 2020 18:24:18
	System	22 Aug 2020 18:24:18

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'de2ddd4c-e8cf-47bb-98ef-12cb88f2729e' User entered '22 Aug 2020 14:24'	System	22 Aug 2020 18:24:18
	System	22 Aug 2020 18:24:18

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 5'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f0fa3674-6d82-41d9-bd3a-a6ba815173ed'	System	23 Aug 2020 19:41:04
User entered 'None (1)'	System	23 Aug 2020 19:41:04

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f0fa3674-6d82-41d9-bd3a-a6ba815173ed' User entered 'No (N)'	System	23 Aug 2020 19:41:04
	System	23 Aug 2020 19:41:04

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f0fa3674-6d82-41d9-bd3a-a6ba815173ed' User entered 'No (N)'	System	23 Aug 2020 19:41:04
	System	23 Aug 2020 19:41:04

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:40:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f0fa3674-6d82-41d9-bd3a-a6ba815173ed' User entered 'None (1)'	System	23 Aug 2020 19:41:04
	System	23 Aug 2020 19:41:04

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:01', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f0fa3674-6d82-41d9-bd3a-a6ba815173ed' User entered '23 Aug 2020 15:41'	System	23 Aug 2020 19:41:04
	System	23 Aug 2020 19:41:04

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 6'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:38', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62028bfa-c9a3-43f9-8fd3-b5aaf5e453d7'	System	24 Aug 2020 18:47:49
User entered 'None (1)'	System	24 Aug 2020 18:47:49

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:40', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62028bfa-c9a3-43f9-8fd3-b5aaf5e453d7' User entered 'No (N)'	System	24 Aug 2020 18:47:49
	System	24 Aug 2020 18:47:49

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:42', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62028bfa-c9a3-43f9-8fd3-b5aaf5e453d7' User entered 'No (N)'	System	24 Aug 2020 18:47:49
	System	24 Aug 2020 18:47:49

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:44', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62028bfa-c9a3-43f9-8fd3-b5aaf5e453d7'	System	24 Aug 2020 18:47:49
User entered 'None (1)'	System	24 Aug 2020 18:47:49

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:46', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62028bfa-c9a3-43f9-8fd3-b5aaf5e453d7' User entered '24 Aug 2020 14:47'	System	24 Aug 2020 18:47:49
	System	24 Aug 2020 18:47:49

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 7'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:27', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9eb98b17-e0e2-442c-9d17-5eba50726333'	System	25 Aug 2020 22:06:38
User entered 'None (1)'	System	25 Aug 2020 22:06:38

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9eb98b17-e0e2-442c-9d17-5eba50726333' User entered 'No (N)'	System	25 Aug 2020 22:06:38
	System	25 Aug 2020 22:06:38

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:31', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9eb98b17-e0e2-442c-9d17-5eba50726333' User entered 'No (N)'	System	25 Aug 2020 22:06:38
	System	25 Aug 2020 22:06:38

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:33', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9eb98b17-e0e2-442c-9d17-5eba50726333'	System	25 Aug 2020 22:06:38
User entered 'None (1)'	System	25 Aug 2020 22:06:38

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:36', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9eb98b17-e0e2-442c-9d17-5eba50726333' User entered '25 Aug 2020 18:06'	System	25 Aug 2020 22:06:38
	System	25 Aug 2020 22:06:38

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:42', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245' User entered 'None (0)'	System	19 Aug 2020 21:29:59
	System	19 Aug 2020 21:29:59

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:44', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245' User entered 'None (0)'	System	19 Aug 2020 21:29:59
	System	19 Aug 2020 21:29:59

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:46', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245'	System	19 Aug 2020 21:29:59
User entered 'None (0)'	System	19 Aug 2020 21:29:59

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245' User entered 'None (0)'	System	19 Aug 2020 21:29:59
	System	19 Aug 2020 21:29:59

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245'	System	19 Aug 2020 21:29:59
User entered 'None (0)'	System	19 Aug 2020 21:29:59

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:51', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245'	System	19 Aug 2020 21:29:59
User entered 'None (0)'	System	19 Aug 2020 21:29:59

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245'	System	19 Aug 2020 21:29:59
User entered 'No (N)'	System	19 Aug 2020 21:29:59

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T17:29:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ad16fdf1-dcfa-4159-b57b-ea53c099b245' User entered '19 Aug 2020 17:29'	System	19 Aug 2020 21:29:59
	System	19 Aug 2020 21:29:59

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Aug 2020 17:01'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Aug 2020 19:31'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 1, after vaccination (at home)'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered 'None (0)'	System	20 Aug 2020 00:27:48
	System	20 Aug 2020 00:27:48

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:24', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered 'None (0)'	System	20 Aug 2020 00:27:48
	System	20 Aug 2020 00:27:48

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:27', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered 'None (0)'	System	20 Aug 2020 00:27:48
	System	20 Aug 2020 00:27:48

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered 'None (0)'	System	20 Aug 2020 00:27:48
	System	20 Aug 2020 00:27:48

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:33', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered 'None (0)'	System	20 Aug 2020 00:27:48
	System	20 Aug 2020 00:27:48

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:37', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered 'None (0)'	System	20 Aug 2020 00:27:48
	System	20 Aug 2020 00:27:48

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:42', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered 'No (N)'	System	20 Aug 2020 00:27:48
	System	20 Aug 2020 00:27:48

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-19T20:27:45', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1e60d67c-2eb0-4430-84eb-07908f4de335' User entered '19 Aug 2020 20:27'	System	20 Aug 2020 00:27:48
	System	20 Aug 2020 00:27:48

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Aug 2020 20:26'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '20 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 2'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:47', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' User entered 'None (0)'	System	20 Aug 2020 18:25:05
	System	20 Aug 2020 18:25:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' User entered 'None (0)'	System	20 Aug 2020 18:25:05
	System	20 Aug 2020 18:25:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' User entered 'None (0)'	System	20 Aug 2020 18:25:05
	System	20 Aug 2020 18:25:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' User entered 'None (0)'	System	20 Aug 2020 18:25:05
	System	20 Aug 2020 18:25:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:54', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' User entered 'None (0)'	System	20 Aug 2020 18:25:05
	System	20 Aug 2020 18:25:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' User entered 'None (0)'	System	20 Aug 2020 18:25:05
	System	20 Aug 2020 18:25:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:24:59', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' User entered 'No (N)'	System	20 Aug 2020 18:25:05
	System	20 Aug 2020 18:25:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-20T14:25:02', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '89f8e7a5-8180-4a91-9298-5d8154c29342' User entered '20 Aug 2020 14:25'	System	20 Aug 2020 18:25:05
	System	20 Aug 2020 18:25:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '20 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '21 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 3'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered 'None (0)'	System	21 Aug 2020 18:15:14
	System	21 Aug 2020 18:15:14

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:14:58', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered 'None (0)'	System	21 Aug 2020 18:15:14
	System	21 Aug 2020 18:15:14

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:15:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered 'None (0)'	System	21 Aug 2020 18:15:14
	System	21 Aug 2020 18:15:14

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:15:02', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered 'None (0)'	System	21 Aug 2020 18:15:14
	System	21 Aug 2020 18:15:14

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:15:04', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered 'None (0)'	System	21 Aug 2020 18:15:14
	System	21 Aug 2020 18:15:14

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:15:05', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered 'None (0)'	System	21 Aug 2020 18:15:14
	System	21 Aug 2020 18:15:14

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:15:08', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered 'No (N)'	System	21 Aug 2020 18:15:14
	System	21 Aug 2020 18:15:14

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-21T14:15:10', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '93bf3766-7293-4c5c-92c6-5468804f80cc' User entered '21 Aug 2020 14:15'	System	21 Aug 2020 18:15:14
	System	21 Aug 2020 18:15:14

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '21 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '22 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 4'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:18', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered 'None (0)'	System	22 Aug 2020 18:24:40
	System	22 Aug 2020 18:24:40

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered 'None (0)'	System	22 Aug 2020 18:24:40
	System	22 Aug 2020 18:24:40

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:22', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered 'None (0)'	System	22 Aug 2020 18:24:40
	System	22 Aug 2020 18:24:40

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:24', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered 'None (0)'	System	22 Aug 2020 18:24:40
	System	22 Aug 2020 18:24:40

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:27', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered 'None (0)'	System	22 Aug 2020 18:24:40
	System	22 Aug 2020 18:24:40

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered 'None (0)'	System	22 Aug 2020 18:24:40
	System	22 Aug 2020 18:24:40

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:34', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered 'No (N)'	System	22 Aug 2020 18:24:40
	System	22 Aug 2020 18:24:40

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-22T14:24:37', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b47807be-62ef-49d6-8908-010e51a85a63' User entered '22 Aug 2020 14:24'	System	22 Aug 2020 18:24:40
	System	22 Aug 2020 18:24:40

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '22 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '23 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 5'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered 'None (0)'	System	23 Aug 2020 19:41:25
	System	23 Aug 2020 19:41:25

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:09', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered 'None (0)'	System	23 Aug 2020 19:41:25
	System	23 Aug 2020 19:41:25

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4'	System	23 Aug 2020 19:41:25
User entered 'None (0)'	System	23 Aug 2020 19:41:25

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:13', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered 'None (0)'	System	23 Aug 2020 19:41:25
	System	23 Aug 2020 19:41:25

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:15', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered 'None (0)'	System	23 Aug 2020 19:41:25
	System	23 Aug 2020 19:41:25

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:17', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered 'None (0)'	System	23 Aug 2020 19:41:25
	System	23 Aug 2020 19:41:25

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered 'No (N)'	System	23 Aug 2020 19:41:25
	System	23 Aug 2020 19:41:25

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-23T15:41:21', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dc536325-3623-40e7-80b6-4ddf277e26f4' User entered '23 Aug 2020 15:41'	System	23 Aug 2020 19:41:25
	System	23 Aug 2020 19:41:25

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '23 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '24 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 6'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:49', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered 'None (0)'	System	24 Aug 2020 18:48:05
	System	24 Aug 2020 18:48:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:51', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered 'None (0)'	System	24 Aug 2020 18:48:05
	System	24 Aug 2020 18:48:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered 'None (0)'	System	24 Aug 2020 18:48:05
	System	24 Aug 2020 18:48:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:54', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered 'None (0)'	System	24 Aug 2020 18:48:05
	System	24 Aug 2020 18:48:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered 'None (0)'	System	24 Aug 2020 18:48:05
	System	24 Aug 2020 18:48:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:57', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered 'None (0)'	System	24 Aug 2020 18:48:05
	System	24 Aug 2020 18:48:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:47:58', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered 'No (N)'	System	24 Aug 2020 18:48:05
	System	24 Aug 2020 18:48:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-24T14:48:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dbd9c4-ea29-466e-b6d1-a9b62d7c081e' User entered '24 Aug 2020 14:48'	System	24 Aug 2020 18:48:05
	System	24 Aug 2020 18:48:05

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '24 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '25 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 7'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:40', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered 'None (0)'	System	25 Aug 2020 22:06:54
	System	25 Aug 2020 22:06:54

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:41', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered 'None (0)'	System	25 Aug 2020 22:06:54
	System	25 Aug 2020 22:06:54

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:42', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered 'None (0)'	System	25 Aug 2020 22:06:54
	System	25 Aug 2020 22:06:54

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:44', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered 'None (0)'	System	25 Aug 2020 22:06:54
	System	25 Aug 2020 22:06:54

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:45', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered 'None (0)'	System	25 Aug 2020 22:06:54
	System	25 Aug 2020 22:06:54

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:46', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered 'None (0)'	System	25 Aug 2020 22:06:54
	System	25 Aug 2020 22:06:54

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:49', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered 'No (N)'	System	25 Aug 2020 22:06:54
	System	25 Aug 2020 22:06:54

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-08-25T18:06:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '65034a34-242c-4c64-b6ce-6b019d2ac199' User entered '25 Aug 2020 18:06'	System	25 Aug 2020 22:06:54
	System	25 Aug 2020 22:06:54

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '25 Aug 2020 12:00'	System	19 Aug 2020 20:51:16

US3172224

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '26 Aug 2020 11:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 16:23:29

US3172224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '26 Aug 2020'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 16:23:29

US3172224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 16:23:29

US3172224

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 16:23:29

US3172224

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	31 Aug 2020 16:23:35

US3172224

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '1'	System	31 Aug 2020 16:23:35

US3172224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:05:37

US3172224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '02 Sep 2020'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:05:37

US3172224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:05:37

US3172224

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:05:37

US3172224

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:37:38

US3172224

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '1'	System	16 Sep 2020 19:37:38

US3172224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:07:06

US3172224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '09 Sep 2020'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:07:06

US3172224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:07:06

US3172224

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:07:06

US3172224

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:37:50

US3172224

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '1'	System	16 Sep 2020 19:37:50

US3172224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:40:08

US3172224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:40:08

US3172224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:40:08

US3172224

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'VISIT2'	System	16 Sep 2020 19:40:08

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '14:25'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '16 Sep 2020 14:25'	System	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '37.1' C	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '95'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'bpm'	System	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '16'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'breaths/min'	System	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '91'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'mmHg'	System	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '75'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'mmHg'	System	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '15:58'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '16 Sep 2020 15:58'	System	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '37.1' C	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '91'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'bpm'	System	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '14'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'breaths/min'	System	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '121'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'mmHg'	System	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '76'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'mmHg'	System	17 Sep 2020 19:19:26

US3172224

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:07:32

US3172224

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:07:32

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:38:45

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:38:45

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:38:45

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 19:38:45

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:38:45

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '15:28'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:38:45

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '16 Sep 2020 15:28'	System	16 Sep 2020 19:38:45

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Right Arm (RIGHT ARM)'	Jessie Downs (b) (4) (b) (4)	16 Sep 2020 19:38:45

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'ONCE'	System	16 Sep 2020 19:38:45

US3172224

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 19:38:45

US3172224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:07:51

US3172224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:07:51

US3172224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '15:17'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:07:51

US3172224

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '16 Sep 2020 15:17'	System	17 Sep 2020 19:07:51

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:33:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '16 Sep 2020'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:08:34

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:08:34

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:08:34

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '15:13'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:08:34

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '16 Sep 2020 15:13'	System	17 Sep 2020 19:08:34

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:08:34

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:08:34

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '15:13'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:08:34

US3172224

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '16 Sep 2020 15:13'	System	17 Sep 2020 19:08:34

US3172224

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Sep 2020 19:07:14

US3172224

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '1'	System	17 Sep 2020 19:07:14

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'e70509fc-72ac-4dd1-ba9b-b7249a87bf0d' User entered 'Yes (Y)'	System	16 Sep 2020 19:58:27
	System	16 Sep 2020 19:58:27

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:17', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'e70509fc-72ac-4dd1-ba9b-b7249a87bf0d' User entered '98.9'	System	16 Sep 2020 19:58:27
	System	16 Sep 2020 19:58:27

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'e70509fc-72ac-4dd1-ba9b-b7249a87bf0d' User entered 'No (N)'	System	16 Sep 2020 19:58:27
	System	16 Sep 2020 19:58:27

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:22', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'e70509fc-72ac-4dd1-ba9b-b7249a87bf0d' User entered '16 Sep 2020 15:58'	System	16 Sep 2020 19:58:27
	System	16 Sep 2020 19:58:27

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '16 Sep 2020 15:48'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '16 Sep 2020 18:18'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:12', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '17ee72af-6a66-41ed-8004-4e62ed7e0193' User entered 'Yes (Y)'	System	16 Sep 2020 23:34:28
	System	16 Sep 2020 23:34:28

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '17ee72af-6a66-41ed-8004-4e62ed7e0193' User entered '97.7'	System	16 Sep 2020 23:34:28
	System	16 Sep 2020 23:34:28

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:23', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '17ee72af-6a66-41ed-8004-4e62ed7e0193'	System	16 Sep 2020 23:34:28
User entered 'No (N)'	System	16 Sep 2020 23:34:28

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:27', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '17ee72af-6a66-41ed-8004-4e62ed7e0193'	System	16 Sep 2020 23:34:28
User entered '16 Sep 2020 19:34'	System	16 Sep 2020 23:34:28

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '16 Sep 2020 19:13'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 2'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:01', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ba168a0a-2be3-45ac-a703-947e1662a563' User entered 'Yes (Y)'	System	17 Sep 2020 16:04:46
	System	17 Sep 2020 16:04:46

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ba168a0a-2be3-45ac-a703-947e1662a563' User entered '98.8'	System	17 Sep 2020 16:04:46
	System	17 Sep 2020 16:04:46

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:12', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ba168a0a-2be3-45ac-a703-947e1662a563' User entered 'No (N)'	System	17 Sep 2020 16:04:46
	System	17 Sep 2020 16:04:46

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:15', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'ba168a0a-2be3-45ac-a703-947e1662a563' User entered '17 Sep 2020 12:03'	System	17 Sep 2020 16:04:46
	System	17 Sep 2020 16:04:46

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 3'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:07:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2b96f4e1-0295-47d3-bb4d-c46a259a5d6c' User entered 'Yes (Y)'	System	18 Sep 2020 16:08:11
	System	18 Sep 2020 16:08:11

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:02', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2b96f4e1-0295-47d3-bb4d-c46a259a5d6c' User entered '98.5'	System	18 Sep 2020 16:08:11
	System	18 Sep 2020 16:08:11

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:05', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2b96f4e1-0295-47d3-bb4d-c46a259a5d6c' User entered 'No (N)'	System	18 Sep 2020 16:08:11
	System	18 Sep 2020 16:08:11

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2b96f4e1-0295-47d3-bb4d-c46a259a5d6c' User entered '18 Sep 2020 12:08'	System	18 Sep 2020 16:08:11
	System	18 Sep 2020 16:08:11

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 4'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:33:44', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8fc0a9aa-091b-49a0-b2f3-590e64ee1380'	System	19 Sep 2020 20:33:56
User entered 'Yes (Y)'	System	19 Sep 2020 20:33:56

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:33:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8fc0a9aa-091b-49a0-b2f3-590e64ee1380' User entered '98.8'	System	19 Sep 2020 20:33:56
	System	19 Sep 2020 20:33:56

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:33:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8fc0a9aa-091b-49a0-b2f3-590e64ee1380'	System	19 Sep 2020 20:33:56
User entered 'No (N)'	System	19 Sep 2020 20:33:56

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:33:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8fc0a9aa-091b-49a0-b2f3-590e64ee1380' User entered '19 Sep 2020 16:33'	System	19 Sep 2020 20:33:56
	System	19 Sep 2020 20:33:56

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 5'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:06:47', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '06f2d214-beb0-4129-a66a-27bbb9c8f076' User entered 'Yes (Y)'	System	20 Sep 2020 16:07:00
	System	20 Sep 2020 16:07:00

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:06:54', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '06f2d214-beb0-4129-a66a-27bbb9c8f076' User entered '98.4'	System	20 Sep 2020 16:07:00
	System	20 Sep 2020 16:07:00

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:06:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '06f2d214-beb0-4129-a66a-27bbb9c8f076' User entered 'No (N)'	System	20 Sep 2020 16:07:00
	System	20 Sep 2020 16:07:00

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:06:58', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '06f2d214-beb0-4129-a66a-27bbb9c8f076' User entered '20 Sep 2020 12:06'	System	20 Sep 2020 16:07:00
	System	20 Sep 2020 16:07:00

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 6'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:23', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b9facc29-efdd-4720-b633-8a495149d2c3' User entered 'Yes (Y)'	System	21 Sep 2020 16:51:37
	System	21 Sep 2020 16:51:37

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b9facc29-efdd-4720-b633-8a495149d2c3' User entered '98.8'	System	21 Sep 2020 16:51:37
	System	21 Sep 2020 16:51:37

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:31', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b9facc29-efdd-4720-b633-8a495149d2c3' User entered 'No (N)'	System	21 Sep 2020 16:51:37
	System	21 Sep 2020 16:51:37

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:34', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b9facc29-efdd-4720-b633-8a495149d2c3' User entered '21 Sep 2020 12:51'	System	21 Sep 2020 16:51:37
	System	21 Sep 2020 16:51:37

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 7'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:52:51', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1a182d4d-dab2-450d-9892-e7bb6f96841e' User entered 'Yes (Y)'	System	22 Sep 2020 19:53:18
	System	22 Sep 2020 19:53:18

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:52:57', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1a182d4d-dab2-450d-9892-e7bb6f96841e' User entered '98.8'	System	22 Sep 2020 19:53:18
	System	22 Sep 2020 19:53:18

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:01', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1a182d4d-dab2-450d-9892-e7bb6f96841e' User entered 'Yes (Y)'	System	22 Sep 2020 19:53:18
	System	22 Sep 2020 19:53:18

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
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 'Data updated in conmed log' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 03:56:53
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.'	Mariete Rendon (b) (4)	25 Sep 2020 17:17:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1a182d4d-dab2-450d-9892-e7bb6f96841e'	System	22 Sep 2020 19:53:18
User entered '1'	System	22 Sep 2020 19:53:18

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1a182d4d-dab2-450d-9892-e7bb6f96841e' User entered '0'	System	22 Sep 2020 19:53:18
	System	22 Sep 2020 19:53:18

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:13', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1a182d4d-dab2-450d-9892-e7bb6f96841e' User entered '22 Sep 2020 15:53'	System	22 Sep 2020 19:53:18
	System	22 Sep 2020 19:53:18

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	22 Sep 2020 19:53:18
User entered 'Day 8'	System	22 Sep 2020 19:53:18

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-23T12:34:05', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'aeaf8904-b8db-422a-962b-5c97396204a5' User entered 'Yes (Y)'	System	23 Sep 2020 16:34:20
	System	23 Sep 2020 16:34:20

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:33:17

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-23T12:34:10', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'aeaf8904-b8db-422a-962b-5c97396204a5' User entered '97.6'	System	23 Sep 2020 16:34:20
	System	23 Sep 2020 16:34:20

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-23T12:34:12', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'aeaf8904-b8db-422a-962b-5c97396204a5' User entered 'No (N)'	System	23 Sep 2020 16:34:20
	System	23 Sep 2020 16:34:20

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-23T12:34:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'aeaf8904-b8db-422a-962b-5c97396204a5' User entered '23 Sep 2020 12:34'	System	23 Sep 2020 16:34:20
	System	23 Sep 2020 16:34:20

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 19:53:18

US3172224

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 19:53:18

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc95bf49-82ef-4f00-9165-2cfa6fa7b09c'	System	16 Sep 2020 19:58:44
User entered 'None (1)'	System	16 Sep 2020 19:58:44

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:35', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc95bf49-82ef-4f00-9165-2cfa6fa7b09c'	System	16 Sep 2020 19:58:44
User entered 'No (N)'	System	16 Sep 2020 19:58:44

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:37', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc95bf49-82ef-4f00-9165-2cfa6fa7b09c'	System	16 Sep 2020 19:58:44
User entered 'No (N)'	System	16 Sep 2020 19:58:44

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:40', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc95bf49-82ef-4f00-9165-2cfa6fa7b09c'	System	16 Sep 2020 19:58:44
User entered 'None (1)'	System	16 Sep 2020 19:58:44

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:42', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc95bf49-82ef-4f00-9165-2cfa6fa7b09c'	System	16 Sep 2020 19:58:44
User entered '16 Sep 2020 15:58'	System	16 Sep 2020 19:58:44

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '16 Sep 2020 15:48'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '16 Sep 2020 18:18'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:32', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'da78f0b6-111b-42c0-b10a-ab3bf6dd5a90' User entered 'None (1)'	System	16 Sep 2020 23:34:43
	System	16 Sep 2020 23:34:43

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:34', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'da78f0b6-111b-42c0-b10a-ab3bf6dd5a90' User entered 'No (N)'	System	16 Sep 2020 23:34:43
	System	16 Sep 2020 23:34:43

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:36', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'da78f0b6-111b-42c0-b10a-ab3bf6dd5a90'	System	16 Sep 2020 23:34:43
User entered 'No (N)'	System	16 Sep 2020 23:34:43

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:39', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'da78f0b6-111b-42c0-b10a-ab3bf6dd5a90' User entered 'None (1)'	System	16 Sep 2020 23:34:43
	System	16 Sep 2020 23:34:43

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:41', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'da78f0b6-111b-42c0-b10a-ab3bf6dd5a90' User entered '16 Sep 2020 19:34'	System	16 Sep 2020 23:34:43
	System	16 Sep 2020 23:34:43

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '16 Sep 2020 19:13'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 2'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '85dfc8f7-9554-4bcb-8ecb-6a28d0f98d26'	System	17 Sep 2020 16:04:54
User entered 'None (1)'	System	17 Sep 2020 16:04:54

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:21', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '85dfc8f7-9554-4bcb-8ecb-6a28d0f98d26'	System	17 Sep 2020 16:04:54
User entered 'No (N)'	System	17 Sep 2020 16:04:54

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:24', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '85dfc8f7-9554-4bcb-8ecb-6a28d0f98d26'	System	17 Sep 2020 16:04:54
User entered 'No (N)'	System	17 Sep 2020 16:04:54

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:32', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '85dfc8f7-9554-4bcb-8ecb-6a28d0f98d26'	System	17 Sep 2020 16:04:54
User entered 'None (1)'	System	17 Sep 2020 16:04:54

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:35', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '85dfc8f7-9554-4bcb-8ecb-6a28d0f98d26' User entered '17 Sep 2020 12:03'	System	17 Sep 2020 16:04:54
	System	17 Sep 2020 16:04:54

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 3'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:12', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '4d3d0497-a149-4adc-866c-35ab2e145fa1'	System	18 Sep 2020 16:08:24
User entered 'None (1)'	System	18 Sep 2020 16:08:24

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:15', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '4d3d0497-a149-4adc-866c-35ab2e145fa1' User entered 'No (N)'	System	18 Sep 2020 16:08:24
	System	18 Sep 2020 16:08:24

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:17', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '4d3d0497-a149-4adc-866c-35ab2e145fa1' User entered 'No (N)'	System	18 Sep 2020 16:08:24
	System	18 Sep 2020 16:08:24

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '4d3d0497-a149-4adc-866c-35ab2e145fa1'	System	18 Sep 2020 16:08:24
User entered 'None (1)'	System	18 Sep 2020 16:08:24

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:21', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '4d3d0497-a149-4adc-866c-35ab2e145fa1' User entered '18 Sep 2020 12:08'	System	18 Sep 2020 16:08:24
	System	18 Sep 2020 16:08:24

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 4'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:33:58', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '91aeca53-12e9-4a24-952f-4cfcc628daab' User entered 'None (1)'	System	19 Sep 2020 20:34:08
	System	19 Sep 2020 20:34:08

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '91aeca53-12e9-4a24-952f-4cfcc628daab' User entered 'No (N)'	System	19 Sep 2020 20:34:08
	System	19 Sep 2020 20:34:08

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:02', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '91aeca53-12e9-4a24-952f-4cfcc628daab' User entered 'No (N)'	System	19 Sep 2020 20:34:08
	System	19 Sep 2020 20:34:08

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:03', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '91aeca53-12e9-4a24-952f-4cfcc628daab'	System	19 Sep 2020 20:34:08
User entered 'None (1)'	System	19 Sep 2020 20:34:08

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:06', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '91aeca53-12e9-4a24-952f-4cfcc628daab' User entered '19 Sep 2020 16:34'	System	19 Sep 2020 20:34:08
	System	19 Sep 2020 20:34:08

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 5'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:02', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '27be92a2-f762-4e85-a4a6-9f0d569cb559'	System	20 Sep 2020 16:07:16
User entered 'None (1)'	System	20 Sep 2020 16:07:16

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:04', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '27be92a2-f762-4e85-a4a6-9f0d569cb559' User entered 'No (N)'	System	20 Sep 2020 16:07:16
	System	20 Sep 2020 16:07:16

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '27be92a2-f762-4e85-a4a6-9f0d569cb559' User entered 'No (N)'	System	20 Sep 2020 16:07:16
	System	20 Sep 2020 16:07:16

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:09', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '27be92a2-f762-4e85-a4a6-9f0d569cb559'	System	20 Sep 2020 16:07:16
User entered 'None (1)'	System	20 Sep 2020 16:07:16

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '27be92a2-f762-4e85-a4a6-9f0d569cb559' User entered '20 Sep 2020 12:07'	System	20 Sep 2020 16:07:16
	System	20 Sep 2020 16:07:16

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 6'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:39', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '877d2458-af43-4f2e-bf19-50a3154ee34f' User entered 'None (1)'	System	21 Sep 2020 16:51:49
	System	21 Sep 2020 16:51:49

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:41', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '877d2458-af43-4f2e-bf19-50a3154ee34f' User entered 'No (N)'	System	21 Sep 2020 16:51:49
	System	21 Sep 2020 16:51:49

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:43', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '877d2458-af43-4f2e-bf19-50a3154ee34f' User entered 'No (N)'	System	21 Sep 2020 16:51:49
	System	21 Sep 2020 16:51:49

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:45', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '877d2458-af43-4f2e-bf19-50a3154ee34f' User entered 'None (1)'	System	21 Sep 2020 16:51:49
	System	21 Sep 2020 16:51:49

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:47', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '877d2458-af43-4f2e-bf19-50a3154ee34f' User entered '21 Sep 2020 12:51'	System	21 Sep 2020 16:51:49
	System	21 Sep 2020 16:51:49

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 7'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:16', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c6989f82-6144-40de-824d-b173156c6495' User entered 'None (1)'	System	22 Sep 2020 19:53:35
	System	22 Sep 2020 19:53:35

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c6989f82-6144-40de-824d-b173156c6495' User entered 'No (N)'	System	22 Sep 2020 19:53:35
	System	22 Sep 2020 19:53:35

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c6989f82-6144-40de-824d-b173156c6495' User entered 'No (N)'	System	22 Sep 2020 19:53:35
	System	22 Sep 2020 19:53:35

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:30', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c6989f82-6144-40de-824d-b173156c6495'	System	22 Sep 2020 19:53:35
User entered 'None (1)'	System	22 Sep 2020 19:53:35

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:33', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c6989f82-6144-40de-824d-b173156c6495'	System	22 Sep 2020 19:53:35
User entered '22 Sep 2020 15:53'	System	22 Sep 2020 19:53:35

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:45', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93' User entered 'None (0)'	System	16 Sep 2020 19:59:02
	System	16 Sep 2020 19:59:02

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:47', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93' User entered 'None (0)'	System	16 Sep 2020 19:59:02
	System	16 Sep 2020 19:59:02

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93' User entered 'None (0)'	System	16 Sep 2020 19:59:02
	System	16 Sep 2020 19:59:02

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:49', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93' User entered 'None (0)'	System	16 Sep 2020 19:59:02
	System	16 Sep 2020 19:59:02

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93' User entered 'None (0)'	System	16 Sep 2020 19:59:02
	System	16 Sep 2020 19:59:02

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93' User entered 'None (0)'	System	16 Sep 2020 19:59:02
	System	16 Sep 2020 19:59:02

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93'	System	16 Sep 2020 19:59:02
User entered 'No (N)'	System	16 Sep 2020 19:59:02

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T15:58:57', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '55b6f0f0-4ff3-489a-972e-973fe9a2cf93'	System	16 Sep 2020 19:59:02
User entered '16 Sep 2020 15:58'	System	16 Sep 2020 19:59:02

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '16 Sep 2020 15:48'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '16 Sep 2020 18:18'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:46', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76' User entered 'None (0)'	System	16 Sep 2020 23:35:00
	System	16 Sep 2020 23:35:00

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:47', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76' User entered 'None (0)'	System	16 Sep 2020 23:35:00
	System	16 Sep 2020 23:35:00

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76'	System	16 Sep 2020 23:35:00
User entered 'None (0)'	System	16 Sep 2020 23:35:00

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76' User entered 'None (0)'	System	16 Sep 2020 23:35:00
	System	16 Sep 2020 23:35:00

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:51', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76'	System	16 Sep 2020 23:35:00
User entered 'None (0)'	System	16 Sep 2020 23:35:00

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76' User entered 'None (0)'	System	16 Sep 2020 23:35:00
	System	16 Sep 2020 23:35:00

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76'	System	16 Sep 2020 23:35:00
User entered 'No (N)'	System	16 Sep 2020 23:35:00

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-16T19:34:57', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '2166249c-00de-4afc-bfad-df35b0503b76'	System	16 Sep 2020 23:35:00
User entered '16 Sep 2020 19:34'	System	16 Sep 2020 23:35:00

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '16 Sep 2020 19:13'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 2'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:39', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered 'None (0)'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:41', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered 'None (0)'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:42', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered 'None (0)'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:44', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered 'None (0)'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:46', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered 'None (0)'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered 'None (0)'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered 'No (N)'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-17T12:03:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'dbcd60b6-1161-4c3e-8866-eac7b7868960' User entered '17 Sep 2020 12:03'	System	17 Sep 2020 16:05:03
	System	17 Sep 2020 16:05:03

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 3'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:25', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered 'None (0)'	System	18 Sep 2020 16:08:41
	System	18 Sep 2020 16:08:41

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:27', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered 'None (0)'	System	18 Sep 2020 16:08:41
	System	18 Sep 2020 16:08:41

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:28', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered 'None (0)'	System	18 Sep 2020 16:08:41
	System	18 Sep 2020 16:08:41

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:30', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered 'None (0)'	System	18 Sep 2020 16:08:41
	System	18 Sep 2020 16:08:41

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:31', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered 'None (0)'	System	18 Sep 2020 16:08:41
	System	18 Sep 2020 16:08:41

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:32', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered 'None (0)'	System	18 Sep 2020 16:08:41
	System	18 Sep 2020 16:08:41

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:34', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered 'No (N)'	System	18 Sep 2020 16:08:41
	System	18 Sep 2020 16:08:41

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-18T12:08:36', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f63622b6-2371-416d-9cb8-6f80238aae68' User entered '18 Sep 2020 12:08'	System	18 Sep 2020 16:08:41
	System	18 Sep 2020 16:08:41

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 4'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:12', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered 'None (0)'	System	19 Sep 2020 20:34:26
	System	19 Sep 2020 20:34:26

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:13', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered 'None (0)'	System	19 Sep 2020 20:34:26
	System	19 Sep 2020 20:34:26

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered 'None (0)'	System	19 Sep 2020 20:34:26
	System	19 Sep 2020 20:34:26

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:16', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered 'None (0)'	System	19 Sep 2020 20:34:26
	System	19 Sep 2020 20:34:26

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:17', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered 'None (0)'	System	19 Sep 2020 20:34:26
	System	19 Sep 2020 20:34:26

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:18', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered 'None (0)'	System	19 Sep 2020 20:34:26
	System	19 Sep 2020 20:34:26

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered 'No (N)'	System	19 Sep 2020 20:34:26
	System	19 Sep 2020 20:34:26

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-19T16:34:22', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6bba264f-d7d1-4b33-83bd-acdc76a97d1d' User entered '19 Sep 2020 16:34'	System	19 Sep 2020 20:34:26
	System	19 Sep 2020 20:34:26

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 5'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered 'None (0)'	System	20 Sep 2020 16:07:27
	System	20 Sep 2020 16:07:27

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:15', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered 'None (0)'	System	20 Sep 2020 16:07:27
	System	20 Sep 2020 16:07:27

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:17', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered 'None (0)'	System	20 Sep 2020 16:07:27
	System	20 Sep 2020 16:07:27

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:18', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered 'None (0)'	System	20 Sep 2020 16:07:27
	System	20 Sep 2020 16:07:27

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered 'None (0)'	System	20 Sep 2020 16:07:27
	System	20 Sep 2020 16:07:27

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered 'None (0)'	System	20 Sep 2020 16:07:27
	System	20 Sep 2020 16:07:27

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:21', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered 'No (N)'	System	20 Sep 2020 16:07:27
	System	20 Sep 2020 16:07:27

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-20T12:07:23', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '30569391-cd6d-4913-bf3c-33aec5ce05eb' User entered '20 Sep 2020 12:07'	System	20 Sep 2020 16:07:27
	System	20 Sep 2020 16:07:27

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 6'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032'	System	21 Sep 2020 16:52:08
User entered 'None (0)'	System	21 Sep 2020 16:52:08

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032' User entered 'None (0)'	System	21 Sep 2020 16:52:08
	System	21 Sep 2020 16:52:08

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:58', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032' User entered 'None (0)'	System	21 Sep 2020 16:52:08
	System	21 Sep 2020 16:52:08

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:51:59', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032' User entered 'None (0)'	System	21 Sep 2020 16:52:08
	System	21 Sep 2020 16:52:08

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:52:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032' User entered 'None (0)'	System	21 Sep 2020 16:52:08
	System	21 Sep 2020 16:52:08

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:52:01', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032' User entered 'None (0)'	System	21 Sep 2020 16:52:08
	System	21 Sep 2020 16:52:08

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:52:04', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032' User entered 'No (N)'	System	21 Sep 2020 16:52:08
	System	21 Sep 2020 16:52:08

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-21T12:52:06', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5244e7ec-55db-46ae-bc27-73c3cfc4e032'	System	21 Sep 2020 16:52:08
User entered '21 Sep 2020 12:52'	System	21 Sep 2020 16:52:08

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	16 Sep 2020 19:38:45
User entered 'Day 7'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:36', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered 'None (0)'	System	22 Sep 2020 19:53:52
	System	22 Sep 2020 19:53:52

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:38', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered 'None (0)'	System	22 Sep 2020 19:53:52
	System	22 Sep 2020 19:53:52

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:40', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered 'None (0)'	System	22 Sep 2020 19:53:52
	System	22 Sep 2020 19:53:52

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:43', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered 'None (0)'	System	22 Sep 2020 19:53:52
	System	22 Sep 2020 19:53:52

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:44', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered 'None (0)'	System	22 Sep 2020 19:53:52
	System	22 Sep 2020 19:53:52

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:45', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered 'None (0)'	System	22 Sep 2020 19:53:52
	System	22 Sep 2020 19:53:52

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:46', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered 'No (N)'	System	22 Sep 2020 19:53:52
	System	22 Sep 2020 19:53:52

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-22T15:53:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '3eadec9e-c9fd-44fe-ae4c-c84864f7866a' User entered '22 Sep 2020 15:53'	System	22 Sep 2020 19:53:52
	System	22 Sep 2020 19:53:52

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 19:38:45

US3172224

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	22 Sep 2020 19:53:18
User entered 'Day 8'	System	22 Sep 2020 19:53:18

US3172224

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-23T12:34:18', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8806011c-5e64-4891-9e98-cdda5ee52144' User entered 'No (N)'	System	23 Sep 2020 16:34:23
	System	23 Sep 2020 16:34:23

US3172224

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-09-23T12:34:21', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8806011c-5e64-4891-9e98-cdda5ee52144' User entered '23 Sep 2020 12:34'	System	23 Sep 2020 16:34:23
	System	23 Sep 2020 16:34:23

US3172224

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 19:53:18

US3172224

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 09 Jun 2021 15:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 19:53:18

US3172224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 16:05:12

US3172224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '23 Sep 2020'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 16:05:12

US3172224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 16:05:12

US3172224

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 16:05:12

US3172224

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	24 Sep 2020 16:05:23

US3172224

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '1'	System	24 Sep 2020 16:05:23

US3172224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	01 Oct 2020 13:25:22

US3172224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '30 Sep 2020'	Jessie Downs (b) (4) (b) (4)	01 Oct 2020 13:25:22

US3172224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	01 Oct 2020 13:25:22

US3172224

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Oct 2020 13:25:22

US3172224

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	08 Oct 2020 16:25:27
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	07 Oct 2020 19:53:42
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	01 Oct 2020 13:25:30

US3172224

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '1'	System	08 Oct 2020 16:25:27
User entered empty.	System	07 Oct 2020 19:53:42
User entered '1'	System	01 Oct 2020 13:25:30

US3172224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	08 Oct 2020 16:25:39

US3172224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '07 Oct 2020'	Jessie Downs (b) (4) (b) (4)	08 Oct 2020 16:25:39

US3172224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	08 Oct 2020 16:25:39

US3172224

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	08 Oct 2020 16:25:39

US3172224

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:49:52
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	08 Oct 2020 16:25:44

US3172224

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '1'	System	14 Oct 2020 18:49:52
User entered empty.	System	08 Oct 2020 16:25:44

US3172224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:47
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:50:17

US3172224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:47
User entered '14 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:50:17

US3172224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:47
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:50:17

US3172224

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'VISIT3'	System	14 Oct 2020 18:50:17

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:47
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:47
User entered '14 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:47
User entered '14:19'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '14 Oct 2020 14:19'	System	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:47
User entered '36.9' C	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:47
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:47
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:47
User entered '92'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'bpm'	System	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:47
User entered '18'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'breaths/min'	System	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:47
User entered '116'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'mmHg'	System	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:47
User entered '79'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered 'mmHg'	System	14 Oct 2020 18:51:59

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34

US3172224

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34

US3172224

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:52:12

US3172224

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:52:12

US3172224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:52:25

US3172224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '14 Oct 2020'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:52:25

US3172224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '14:41'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:52:25

US3172224

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '14 Oct 2020 14:41'	System	14 Oct 2020 18:52:25

US3172224

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 16:53:52
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	14 Oct 2020 18:52:28

US3172224

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '1'	System	13 Nov 2020 16:53:52
User entered empty.	System	14 Oct 2020 18:52:28

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 64'	System	19 Aug 2020 20:51:16

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-10-19T06:07:33', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f4450daf-250f-4a84-ac89-c10087c0b045'	System	19 Oct 2020 10:08:03
User entered 'No (N)'	System	19 Oct 2020 10:08:03

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-10-19T06:07:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f4450daf-250f-4a84-ac89-c10087c0b045'	System	19 Oct 2020 10:08:03
User entered 'No (N)'	System	19 Oct 2020 10:08:03

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-10-19T06:07:59', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f4450daf-250f-4a84-ac89-c10087c0b045' User entered '19 Oct 2020 06:07:59'	System	19 Oct 2020 10:08:03
	System	19 Oct 2020 10:08:03

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered '19 Oct 2020 00:01'	System	19 Aug 2020 20:51:16

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered '23 Oct 2020 23:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 71'	System	19 Aug 2020 20:51:16

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-10-26T05:56:57', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc8edf4e-8600-4cb3-93a7-b0d1cbf5a860' User entered 'No (N)'	System	26 Oct 2020 09:57:20
	System	26 Oct 2020 09:57:20

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-10-26T05:57:11', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc8edf4e-8600-4cb3-93a7-b0d1cbf5a860'	System	26 Oct 2020 09:57:20
User entered 'No (N)'	System	26 Oct 2020 09:57:20

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-10-26T05:57:15', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'bc8edf4e-8600-4cb3-93a7-b0d1cbf5a860' User entered '26 Oct 2020 05:57:15'	System	26 Oct 2020 09:57:20
	System	26 Oct 2020 09:57:20

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered '26 Oct 2020 00:01'	System	19 Aug 2020 20:51:16

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered '30 Oct 2020 23:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 78'	System	19 Aug 2020 20:51:16

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-02T06:06:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6786e077-6b0e-40bd-ada9-37697e079386'	System	02 Nov 2020 11:06:22
User entered 'No (N)'	System	02 Nov 2020 11:06:22

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-02T06:06:13', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6786e077-6b0e-40bd-ada9-37697e079386'	System	02 Nov 2020 11:06:22
User entered 'No (N)'	System	02 Nov 2020 11:06:22

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-02T06:06:18', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6786e077-6b0e-40bd-ada9-37697e079386' User entered '02 Nov 2020 06:06:18'	System	02 Nov 2020 11:06:22
	System	02 Nov 2020 11:06:22

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered '02 Nov 2020 00:01'	System	19 Aug 2020 20:51:16

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered '06 Nov 2020 23:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered 'Day 92'	System	19 Aug 2020 20:51:16

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-16T06:20:39', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9482cf04-7c5d-4086-90d2-f4e932190983' User entered 'No (N)'	System	16 Nov 2020 11:20:52
	System	16 Nov 2020 11:20:52

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-16T06:20:45', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9482cf04-7c5d-4086-90d2-f4e932190983' User entered 'No (N)'	System	16 Nov 2020 11:20:52
	System	16 Nov 2020 11:20:52

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-16T06:20:50', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9482cf04-7c5d-4086-90d2-f4e932190983' User entered '16 Nov 2020 06:20:50'	System	16 Nov 2020 11:20:52
	System	16 Nov 2020 11:20:52

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered '16 Nov 2020 00:01'	System	19 Aug 2020 20:51:16

US3172224

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:57:11
Data entry locked.	System	19 Aug 2020 20:51:16
User entered '20 Nov 2020 23:59'	System	19 Aug 2020 20:51:16

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-23T06:03:30', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '78ae8d18-cc53-4615-8af0-dc773faa50a1'	System	23 Nov 2020 11:03:51
User entered 'No (N)'	System	23 Nov 2020 11:03:51

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-23T06:03:45', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '78ae8d18-cc53-4615-8af0-dc773faa50a1'	System	23 Nov 2020 11:03:51
User entered 'No (N)'	System	23 Nov 2020 11:03:51

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-23T06:03:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '78ae8d18-cc53-4615-8af0-dc773faa50a1' User entered '23 Nov 2020 06:03:48'	System	23 Nov 2020 11:03:51
	System	23 Nov 2020 11:03:51

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-27T01:37:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9844db26-1b7c-469a-b8d5-e568217b98ee' User entered 'No (N)'	System	27 Nov 2020 06:37:29
	System	27 Nov 2020 06:37:29

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-27T01:37:25', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9844db26-1b7c-469a-b8d5-e568217b98ee' User entered 'No (N)'	System	27 Nov 2020 06:37:29
	System	27 Nov 2020 06:37:29

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-11-27T01:37:28', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9844db26-1b7c-469a-b8d5-e568217b98ee' User entered '27 Nov 2020 01:37:28'	System	27 Nov 2020 06:37:29
	System	27 Nov 2020 06:37:29

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-05T07:56:55', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b06e3ec3-2f8f-433e-9f94-633b04198b10'	System	05 Dec 2020 12:57:04
User entered 'No (N)'	System	05 Dec 2020 12:57:04

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-05T07:56:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b06e3ec3-2f8f-433e-9f94-633b04198b10'	System	05 Dec 2020 12:57:04
User entered 'No (N)'	System	05 Dec 2020 12:57:04

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-05T07:56:59', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b06e3ec3-2f8f-433e-9f94-633b04198b10' User entered '05 Dec 2020 07:56:59'	System	05 Dec 2020 12:57:04
	System	05 Dec 2020 12:57:04

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-11T05:55:52', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8edfb976-c674-4ced-b6ff-4d325a272a5d'	System	11 Dec 2020 10:56:03
User entered 'No (N)'	System	11 Dec 2020 10:56:03

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-11T05:55:56', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8edfb976-c674-4ced-b6ff-4d325a272a5d'	System	11 Dec 2020 10:56:03
User entered 'No (N)'	System	11 Dec 2020 10:56:03

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-11T05:55:59', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8edfb976-c674-4ced-b6ff-4d325a272a5d' User entered '11 Dec 2020 05:55:59'	System	11 Dec 2020 10:56:03
	System	11 Dec 2020 10:56:03

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-18T05:52:51', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dee4c4-f707-44d7-b86a-26cf8e18c23a'	System	18 Dec 2020 10:53:00
User entered 'No (N)'	System	18 Dec 2020 10:53:00

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-18T05:52:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dee4c4-f707-44d7-b86a-26cf8e18c23a'	System	18 Dec 2020 10:53:00
User entered 'No (N)'	System	18 Dec 2020 10:53:00

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-18T05:52:57', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c4dee4c4-f707-44d7-b86a-26cf8e18c23a' User entered '18 Dec 2020 05:52:57'	System	18 Dec 2020 10:53:00
	System	18 Dec 2020 10:53:00

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-25T08:59:25', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '950c01cd-bda5-43ca-84fa-00624824247c' User entered 'No (N)'	System	25 Dec 2020 13:59:41
	System	25 Dec 2020 13:59:41

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-25T08:59:37', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '950c01cd-bda5-43ca-84fa-00624824247c' User entered 'No (N)'	System	25 Dec 2020 13:59:41
	System	25 Dec 2020 13:59:41

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2020-12-25T08:59:40', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '950c01cd-bda5-43ca-84fa-00624824247c' User entered '25 Dec 2020 08:59:40'	System	25 Dec 2020 13:59:41
	System	25 Dec 2020 13:59:41

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-01T00:15:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b6e68d1e-b3da-482b-892c-29e9c0c23d67'	System	01 Jan 2021 05:15:31
User entered 'No (N)'	System	01 Jan 2021 05:15:31

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-01T00:15:23', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b6e68d1e-b3da-482b-892c-29e9c0c23d67'	System	01 Jan 2021 05:15:31
User entered 'No (N)'	System	01 Jan 2021 05:15:31

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-01T00:15:29', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'b6e68d1e-b3da-482b-892c-29e9c0c23d67' User entered '01 Jan 2021 00:15:29'	System	01 Jan 2021 05:15:31
	System	01 Jan 2021 05:15:31

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-08T05:52:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '418bea1f-428b-4c6a-b91f-88fc6e541a3c' User entered 'No (N)'	System	08 Jan 2021 10:53:58

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-08T05:53:26', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '418bea1f-428b-4c6a-b91f-88fc6e541a3c'	System	08 Jan 2021 10:53:58
User entered 'Yes (Y)'	System	08 Jan 2021 10:53:58

**US3172224**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

Please 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-08T05:53:43', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '418bea1f-428b-4c6a-b91f-88fc6e541a3c'	System	08 Jan 2021 10:53:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	08 Jan 2021 10:53:58

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-08T05:53:48', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '418bea1f-428b-4c6a-b91f-88fc6e541a3c' User entered '08 Jan 2021 05:53:48'	System	08 Jan 2021 10:53:58
	System	08 Jan 2021 10:53:58

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-15T06:07:26', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '79e47fd3-142f-4981-a807-c570bc0a968b'	System	15 Jan 2021 11:07:38
User entered 'No (N)'	System	15 Jan 2021 11:07:38

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-15T06:07:32', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '79e47fd3-142f-4981-a807-c570bc0a968b'	System	15 Jan 2021 11:07:38
User entered 'No (N)'	System	15 Jan 2021 11:07:38

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-15T06:07:35', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '79e47fd3-142f-4981-a807-c570bc0a968b' User entered '15 Jan 2021 06:07:35'	System	15 Jan 2021 11:07:38
	System	15 Jan 2021 11:07:38

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-22T05:53:07', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7a2a94cb-6309-46b1-af05-3effa8dc683a'	System	22 Jan 2021 10:53:44
User entered 'Yes (Y)'	System	22 Jan 2021 10:53:44

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-22T05:53:14', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7a2a94cb-6309-46b1-af05-3effa8dc683a'	System	22 Jan 2021 10:53:44
User entered 'No (N)'	System	22 Jan 2021 10:53:44

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-22T05:53:24', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7a2a94cb-6309-46b1-af05-3effa8dc683a'	System	22 Jan 2021 10:53:44
User entered 'No (N)'	System	22 Jan 2021 10:53:44

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-22T05:53:34', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7a2a94cb-6309-46b1-af05-3effa8dc683a' User entered 'No (N)'	System	22 Jan 2021 10:53:44
	System	22 Jan 2021 10:53:44

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-22T05:53:41', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7a2a94cb-6309-46b1-af05-3effa8dc683a' User entered '22 Jan 2021 05:53:41'	System	22 Jan 2021 10:53:44

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-29T09:23:57', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8cdc97c8-d274-49a9-b7ca-6b4b626e7850'	System	29 Jan 2021 14:24:31
User entered 'Yes (Y)'	System	29 Jan 2021 14:24:31

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-29T09:24:01', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8cdc97c8-d274-49a9-b7ca-6b4b626e7850'	System	29 Jan 2021 14:24:31
User entered 'No (N)'	System	29 Jan 2021 14:24:31

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-29T09:24:05', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8cdc97c8-d274-49a9-b7ca-6b4b626e7850'	System	29 Jan 2021 14:24:31
User entered 'No (N)'	System	29 Jan 2021 14:24:31

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-29T09:24:12', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8cdc97c8-d274-49a9-b7ca-6b4b626e7850'	System	29 Jan 2021 14:24:31
User entered 'Yes (Y)'	System	29 Jan 2021 14:24:31

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Please 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-29T09:24:16', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8cdc97c8-d274-49a9-b7ca-6b4b626e7850'	System	29 Jan 2021 14:24:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Jan 2021 14:24:31

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-01-29T09:24:20', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '8cdc97c8-d274-49a9-b7ca-6b4b626e7850' User entered '29 Jan 2021 09:24:20'	System	29 Jan 2021 14:24:31
	System	29 Jan 2021 14:24:31

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-05T06:30:46', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6302b9c7-3cae-4097-94de-ec543f94628d'	System	05 Feb 2021 11:30:56
User entered 'No (N)'	System	05 Feb 2021 11:30:56

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-05T06:30:49', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6302b9c7-3cae-4097-94de-ec543f94628d' User entered 'No (N)'	System	05 Feb 2021 11:30:56
	System	05 Feb 2021 11:30:56

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-05T06:30:53', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6302b9c7-3cae-4097-94de-ec543f94628d' User entered '05 Feb 2021 06:30:53'	System	05 Feb 2021 11:30:56
	System	05 Feb 2021 11:30:56

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-12T06:41:06', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'fc111e71-8666-4ab9-bd38-4dd3805aabf1'	System	12 Feb 2021 11:41:17
User entered 'No (N)'	System	12 Feb 2021 11:41:17

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-12T06:41:10', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'fc111e71-8666-4ab9-bd38-4dd3805aabf1'	System	12 Feb 2021 11:41:17
User entered 'No (N)'	System	12 Feb 2021 11:41:17

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-12T06:41:15', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'fc111e71-8666-4ab9-bd38-4dd3805aabf1' User entered '12 Feb 2021 06:41:15'	System	12 Feb 2021 11:41:17
	System	12 Feb 2021 11:41:17

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-21T12:00:19', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'e980b008-16a1-42c5-97dc-74e562030943'	System	21 Feb 2021 17:01:28
User entered 'No (N)'	System	21 Feb 2021 17:01:28

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-21T12:00:22', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'e980b008-16a1-42c5-97dc-74e562030943'	System	21 Feb 2021 17:01:28
User entered 'No (N)'	System	21 Feb 2021 17:01:28

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-21T12:00:25', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'e980b008-16a1-42c5-97dc-74e562030943' User entered '21 Feb 2021 12:00:25'	System	21 Feb 2021 17:01:28
	System	21 Feb 2021 17:01:28

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-26T00:30:14-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9b0c40ba-e76a-4214-aa6b-9cb12057069c'	System	26 Feb 2021 05:30:24
User entered 'No (N)'	System	26 Feb 2021 05:30:24

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-26T00:30:18-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9b0c40ba-e76a-4214-aa6b-9cb12057069c' User entered 'No (N)'	System	26 Feb 2021 05:30:24
	System	26 Feb 2021 05:30:24

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-02-26T00:30:22-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '9b0c40ba-e76a-4214-aa6b-9cb12057069c' User entered '26 Feb 2021 05:30:22'	System	26 Feb 2021 05:30:24
	System	26 Feb 2021 05:30:24

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-05T06:07:34-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62017058-08ed-42a2-b784-4fcd4cb22194'	System	05 Mar 2021 11:07:44
User entered 'No (N)'	System	05 Mar 2021 11:07:44

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-05T06:07:38-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62017058-08ed-42a2-b784-4fcd4cb22194'	System	05 Mar 2021 11:07:44
User entered 'No (N)'	System	05 Mar 2021 11:07:44

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-05T06:07:40-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '62017058-08ed-42a2-b784-4fcd4cb22194'	System	05 Mar 2021 11:07:44
User entered '05 Mar 2021 06:07:40'	System	05 Mar 2021 11:07:44

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-12T05:45:40-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1eeda4f3-7f6c-4db8-b141-b8519af1ebc7'	System	12 Mar 2021 10:45:50
User entered 'No (N)'	System	12 Mar 2021 10:45:50

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-12T05:45:43-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1eeda4f3-7f6c-4db8-b141-b8519af1ebc7'	System	12 Mar 2021 10:45:50
User entered 'No (N)'	System	12 Mar 2021 10:45:50

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-12T05:45:46-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '1eeda4f3-7f6c-4db8-b141-b8519af1ebc7'	System	12 Mar 2021 10:45:50
User entered '12 Mar 2021 05:45:46'	System	12 Mar 2021 10:45:50

**US3172224**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-19T05:28:06-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6083ca33-98ba-4e2c-b7fc-e131b0b71da6'	System	19 Mar 2021 09:28:14
User entered 'No (N)'	System	19 Mar 2021 09:28:14

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-19T05:28:10-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6083ca33-98ba-4e2c-b7fc-e131b0b71da6'	System	19 Mar 2021 09:28:14
User entered 'No (N)'	System	19 Mar 2021 09:28:14

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-19T05:28:12-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '6083ca33-98ba-4e2c-b7fc-e131b0b71da6'	System	19 Mar 2021 09:28:14
User entered '19 Mar 2021 05:28:12'	System	19 Mar 2021 09:28:14

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-26T06:39:39-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '0903a66f-6d70-4fa4-8934-8b7f5788407b' User entered 'No (N)'	System	26 Mar 2021 10:39:51
	System	26 Mar 2021 10:39:51

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-26T06:39:42-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '0903a66f-6d70-4fa4-8934-8b7f5788407b' User entered 'No (N)'	System	26 Mar 2021 10:39:51
	System	26 Mar 2021 10:39:51

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-26T06:39:49-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '0903a66f-6d70-4fa4-8934-8b7f5788407b' User entered '26 Mar 2021 06:39:49'	System	26 Mar 2021 10:39:51
	System	26 Mar 2021 10:39:51

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-02T06:28:23-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '246da140-cc5b-413d-9a5c-b0ac5b3e919b'	System	02 Apr 2021 10:28:36
User entered 'No (N)'	System	02 Apr 2021 10:28:36

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-02T06:28:27-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '246da140-cc5b-413d-9a5c-b0ac5b3e919b'	System	02 Apr 2021 10:28:36
User entered 'No (N)'	System	02 Apr 2021 10:28:36

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-02T06:28:30-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '246da140-cc5b-413d-9a5c-b0ac5b3e919b'	System	02 Apr 2021 10:28:36
User entered '02 Apr 2021 06:28:30'	System	02 Apr 2021 10:28:36

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-09T06:08:47-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c2479a83-4a67-4c33-bed9-8c36ead32c15'	System	09 Apr 2021 10:08:54
User entered 'No (N)'	System	09 Apr 2021 10:08:54

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-09T06:08:49-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c2479a83-4a67-4c33-bed9-8c36ead32c15'	System	09 Apr 2021 10:08:54
User entered 'No (N)'	System	09 Apr 2021 10:08:54

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-09T06:08:51-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'c2479a83-4a67-4c33-bed9-8c36ead32c15' User entered '09 Apr 2021 06:08:51'	System	09 Apr 2021 10:08:54
	System	09 Apr 2021 10:08:54

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-16T06:02:52-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7440e976-0c52-48ee-a197-dc98621949e0'	System	16 Apr 2021 10:03:02
User entered 'No (N)'	System	16 Apr 2021 10:03:02

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-16T06:02:55-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7440e976-0c52-48ee-a197-dc98621949e0'	System	16 Apr 2021 10:03:02
User entered 'No (N)'	System	16 Apr 2021 10:03:02

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-16T06:02:59-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '7440e976-0c52-48ee-a197-dc98621949e0' User entered '16 Apr 2021 06:02:59'	System	16 Apr 2021 10:03:02
	System	16 Apr 2021 10:03:02

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-23T06:06:29-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f8c29dd4-f18c-4b90-92c9-b5c5c73ab32f'	System	23 Apr 2021 10:06:37
User entered 'No (N)'	System	23 Apr 2021 10:06:37

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-23T06:06:32-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f8c29dd4-f18c-4b90-92c9-b5c5c73ab32f'	System	23 Apr 2021 10:06:37
User entered 'No (N)'	System	23 Apr 2021 10:06:37

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-23T06:06:34-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'f8c29dd4-f18c-4b90-92c9-b5c5c73ab32f' User entered '23 Apr 2021 06:06:34'	System	23 Apr 2021 10:06:37
	System	23 Apr 2021 10:06:37

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-30T06:11:28-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'feab3c17-316d-44ce-bd56-693c20083764'	System	30 Apr 2021 10:11:36
User entered 'No (N)'	System	30 Apr 2021 10:11:36

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

Have you been exposed to someone with 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 (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-30T06:11:30-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'feab3c17-316d-44ce-bd56-693c20083764'	System	30 Apr 2021 10:11:36
User entered 'No (N)'	System	30 Apr 2021 10:11:36

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-04-30T06:11:33-04:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: 'feab3c17-316d-44ce-bd56-693c20083764'	System	30 Apr 2021 10:11:36
User entered '30 Apr 2021 06:11:33'	System	30 Apr 2021 10:11:36

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 23:15:15

**US3172224**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:15:15

**US3172224**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:15:15

**US3172224**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:15:15

**US3172224**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:15:15

**US3172224**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:15:15

**US3172224**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 23:15:15

**US3172224**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:15:15

**US3172224**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '21 Oct 2022 00:01'	System	19 Nov 2020 23:15:15

US3172224

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:33:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:15:15
Amendment Manager: User entered '25 Oct 2022 23:59'	System	19 Nov 2020 23:15:15

US3172224

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:33:17

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-05T06:07:47-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5e24828d-2a54-431c-aac5-feb117c1cf1e'	System	05 Mar 2021 11:07:56
User entered 'No (N)'	System	05 Mar 2021 11:07:56

US3172224

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:33:17

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:49:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17F96479-7BBE-44FC-A20A-15D0D042FCA7)', Time: '2021-03-05T06:07:50-05:00', User OID: 'PatientReportedOutcome (US3172224)', ODM File OID: '5e24828d-2a54-431c-aac5-feb117c1cf1e' User entered '05 Mar 2021 06:07:50'	System	05 Mar 2021 11:07:56
	System	05 Mar 2021 11:07:56

US3172224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 16:54:50

US3172224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '12 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 16:54:50

US3172224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Nov 2020 16:54:50

US3172224

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 16:54:50

US3172224

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Nov 2020 16:54:55

US3172224

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:11:34
User entered '1'	System	13 Nov 2020 16:54:55

US3172224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Dec 2020 20:00:40

US3172224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '15 Dec 2020'	Jessie Downs (b) (4) (b) (4)	15 Dec 2020 20:00:40

US3172224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	15 Dec 2020 20:00:40

US3172224

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Dec 2020 20:00:40

US3172224

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Dec 2020 20:00:54

US3172224

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User entered '1'	System	15 Dec 2020 20:00:54

US3172224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 14:48:20

US3172224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 07:33:31
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'Data was updated ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:38:06
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 29JAN2021 under Participant Decision Visit / OL-D1 in PPD central lab, however same is missing in EDC. Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 09:53:43
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4), (b) (6)	22 Jan 2021 05:17:40
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' answered with 'Date confirmed as entered.' (Site from System).	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 14:48:42
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	20 Jan 2021 14:48:20
User entered '18 Jan 2021'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 14:48:20

US3172224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 14:48:20

US3172224

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 14:48:20

US3172224

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	20 Jan 2021 14:48:52

US3172224

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User entered '1'	System	20 Jan 2021 14:48:52

US3172224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Feb 2021 21:48:55

US3172224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '15 Feb 2021'	Jessie Downs (b) (4) (b) (4)	15 Feb 2021 21:48:55

US3172224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	15 Feb 2021 21:48:55

US3172224

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	15 Feb 2021 21:48:55

US3172224

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	15 Feb 2021 21:49:07

US3172224

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 14:01:21
User entered '1'	System	15 Feb 2021 21:49:07

US3172224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Apr 2021 20:12:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 06:48:42
Query 'Data is required. Please complete.' answered with 'Data added in error' (Site from System).	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:58:17
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 19:57:59
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:57:59
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:46:15

US3172224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:57:59
User entered '19 Mar 2021'	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:46:15

US3172224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:57:59
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:46:15

US3172224

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	01 Apr 2021 20:12:05
User entered empty.	System	26 Mar 2021 19:57:59
User entered 'VISIT4'	System	26 Mar 2021 19:46:15

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:36
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	01 Apr 2021 20:12:12

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:36
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Apr 2021 20:12:12

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:36
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Apr 2021 20:12:12

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

---

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 20:12:12

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US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:36
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Apr 2021 20:12:12

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:36
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Apr 2021 20:12:12

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:36
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Apr 2021 20:12:12

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:36
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Apr 2021 20:12:12

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 20:12:12

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US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:36
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Apr 2021 20:12:12

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 20:12:12

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US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:36
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Apr 2021 20:12:12

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 20:12:12

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US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:36
User entered empty.	Jessie Downs (b) (4) (b) (4)	01 Apr 2021 20:12:12

US3172224

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:33:17

[Diastolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 20:12:12

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US3172224

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Apr 2021 20:12:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 06:48:36
Query 'Data is required. Please complete.' answered with 'Data added in error' (Site from System).	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:58:20
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 19:57:48
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:57:48
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:56:47

US3172224

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:56:47

US3172224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Apr 2021 20:12:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 06:53:22
Query 'Data is required. Please complete.' answered with 'Data added in error' (Site from System).	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:58:24
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 19:57:43
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:57:43
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:57:06

US3172224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:57:43
User entered '19 Mar 2021'	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:57:06

US3172224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:57:43
User entered '10:06'	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:57:06

US3172224

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Mar 2021 19:57:43
User entered '19 Mar 2021 10:06'	System	26 Mar 2021 19:57:06

US3172224

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	01 Apr 2021 20:12:28
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 06:48:27
Query 'Data is required. Please complete.' answered with 'Data added in error' (Site from System).	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:58:28
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 19:57:23
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:57:23
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	26 Mar 2021 19:57:10

US3172224

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 20:12:28
User entered empty.	System	26 Mar 2021 19:57:23
User entered '1'	System	26 Mar 2021 19:57:10

US3172224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:26:19

US3172224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '14 Apr 2021'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:26:19

US3172224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:26:19

US3172224

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:26:19

US3172224

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:26:24

US3172224

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

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Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 16:26:24

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US3172224

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

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:35:49

US3172224

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

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '29 Jan 2021'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:35:49

US3172224

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

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:35:49

US3172224

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

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'UNBLND_DECIDE'	System	06 Feb 2021 19:35:49

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User closed query 'PER CDM: RE-QUERY: Per response data updated. However, still date is 22 DEC 2020 and protocol version is Amendment 6 or later. Please review/reconcile and update the data as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 07:19:01
Query 'PER CDM: RE-QUERY: Per response data updated. However, still date is 22 DEC 2020 and protocol version is Amendment 6 or later. Please review/reconcile and update the data as appropriate. Thank you' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 14:49:20
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 14:48:58
User entered '06 Jan 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	20 Apr 2021 14:48:58
User opened query 'PER CDM: RE-QUERY: Per response data updated. However, still date is 22 DEC 2020 and protocol version is Amendment 6 or later. Please review/reconcile and update the data as appropriate. Thank you' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:37:35
User closed query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:37:35

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 19:59:05
User opened query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Mark Kutner (b) (4) (b) (4)	07 Apr 2021 17:20:35 17 Feb 2021 13:11:39
User entered '22 Dec 2020'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:37:26

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:14:01
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:06:46

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:37:26

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
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 field.	(b) (4), (b) (6)	15 Apr 2021 20:06:18
' (Site from DM). 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 field.	(b) (4), (b) (6)	12 Apr 2021 13:06:03
' answered with 'Data updated' (Site from DM). User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:05:36
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 field.	(b) (4), (b) (6)	09 Apr 2021 21:42:13
' (Site from DM). Signature has been broken.	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 19:58:51
User entered 'Amendment 5 (Amendment 5)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	07 Apr 2021 19:58:51
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:14:01
User entered empty. WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:06:46

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User closed query 'Per IRT, subject was unblinded on 29JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 20:06:20
Query 'Per IRT, subject was unblinded on 29JAN2021. Please review and reconcile.' answered with 'Data updated ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 13:06:21
User entered '29 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 13:05:36
User opened query 'Per IRT, subject was unblinded on 29JAN2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:10:39
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:00:48
User entered '19 Mar 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:00:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '29 Jan 2021'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:37:26

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:37:26

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:37:26

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:37:26

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:00:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:00:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:37:26

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '1'	System	06 Feb 2021 19:37:26

US3172224

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

Form: Unblinding

Generated On: 09 Jun 2021 15:33:17

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '1'	System	22 Mar 2021 19:00:48
User entered empty.	System	06 Feb 2021 19:37:26

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '079.7' kg	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered empty.	System	22 Mar 2021 19:02:58
DataPoint set to visible.	System	22 Mar 2021 19:00:48

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '079.7' kg	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered empty.	System	22 Mar 2021 19:02:58
DataPoint set to visible.	System	22 Mar 2021 19:00:48

US3172224

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '19 Mar 2021'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '13:10'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '19 Mar 2021 13:10'	System	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '37.2' C	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '89'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'bpm'	System	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '17'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'breaths/min'	System	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '112'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'mmHg'	System	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '73'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'mmHg'	System	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '079.7' kg	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:33:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered empty.	System	22 Mar 2021 19:02:58
DataPoint set to visible.	System	22 Mar 2021 19:00:48

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '19 Mar 2021'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '15:12'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '19 Mar 2021 15:12'	System	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '36.6' C	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '61'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'bpm'	System	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '16'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'breaths/min'	System	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '123'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'mmHg'	System	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '80'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'mmHg'	System	22 Mar 2021 19:02:58

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:01:11

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '19 Mar 2021'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:01:11

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:01:30

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:01:30

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:01:30

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'mRNA-1273'	System	22 Mar 2021 19:01:30
DataPoint set to visible.	System	22 Mar 2021 19:00:48

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '19 Mar 2021'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:01:30

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '14:42'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:01:30

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '19 Mar 2021 14:42'	System	22 Mar 2021 19:01:30

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Right Arm (RIGHT ARM)'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:01:30

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'ONCE'	System	22 Mar 2021 19:01:30

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered 'INTRAMUSCULAR'	System	22 Mar 2021 19:01:30

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:36:11

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '29 Jan 2021'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:36:11

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '13:35'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:36:11

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '29 Jan 2021 13:35'	System	06 Feb 2021 19:36:11

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:36:37

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '29 Jan 2021'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:36:37

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '13:36'	Jessie Downs (b) (4) (b) (4)	06 Feb 2021 19:36:37

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:33:17

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '29 Jan 2021 13:36'	System	06 Feb 2021 19:36:37

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 19:01:34

US3172224

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:21:53
User entered '1'	System	22 Mar 2021 19:01:34

US3172224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	Jessie Downs (b) (4)	26 Mar 2021 19:31:46

US3172224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:33
User entered '26 Mar 2021'	Jessie Downs (b) (4)	26 Mar 2021 19:31:46

US3172224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:33
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	26 Mar 2021 19:31:46

US3172224

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:33
User entered empty.	Jessie Downs (b) (4)	26 Mar 2021 19:31:46

US3172224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:32
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	Jessie Downs (b) (4)	26 Mar 2021 19:32:34

US3172224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:32
User entered '1'	System	26 Mar 2021 19:32:34

US3172224

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:42:32
User entered '1'	System	26 Mar 2021 19:32:34
DataPoint set to visible.	System	26 Mar 2021 19:32:34

US3172224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 20:23:20

US3172224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '13 Apr 2021'	(b) (4), (b) (6)	21 Apr 2021 20:23:20

US3172224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Apr 2021 20:23:20

US3172224

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:33:17

[Folder OID](#)

---

Audit	User	Time (GMT)
User entered 'OLD29'	System	21 Apr 2021 20:23:20

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US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '13 Apr 2021'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '13:50'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Vital Signs Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '13 Apr 2021 13:50'	System	21 Apr 2021 20:24:50

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US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '36.7' C	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '80'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Apr 2021 20:24:50

---

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '15'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

---

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Apr 2021 20:24:50

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US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '108'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Apr 2021 20:24:50

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US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '72'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:33:17

[Diastolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Apr 2021 20:24:50

---

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '13 Apr 2021'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '15:23'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Vital Signs Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '13 Apr 2021 15:23'	System	21 Apr 2021 20:24:50

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US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '36.8' C	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '60'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Apr 2021 20:24:50

---

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '16'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Respiratory Rate units](#)

---

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Apr 2021 20:24:50

---

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '122'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Apr 2021 20:24:50

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US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '78'	(b) (4), (b) (6)	21 Apr 2021 20:24:50

US3172224

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:33:17

[Diastolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Apr 2021 20:24:50

---

US3172224

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 20:24:56

US3172224

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:33:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:24:56

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 20:25:25

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:25:25

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:25:25

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	21 Apr 2021 20:25:25
DataPoint set to visible.	System	26 Mar 2021 19:32:34

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '13 Apr 2021'	(b) (4), (b) (6)	21 Apr 2021 20:25:25

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '14:53'	(b) (4), (b) (6)	21 Apr 2021 20:25:25

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[Treatment Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered '13 Apr 2021 14:53'	System	21 Apr 2021 20:25:25

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US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	21 Apr 2021 20:25:25

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	21 Apr 2021 20:25:25

US3172224

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:33:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	21 Apr 2021 20:25:25

US3172224

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 20:25:32

US3172224

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

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Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 20:25:32

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US3172224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 20:25:48

US3172224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered '21 Apr 2021'	(b) (4), (b) (6)	21 Apr 2021 20:25:48

US3172224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	21 Apr 2021 20:25:48

US3172224

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:25:48

US3172224

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Apr 2021 20:25:54

US3172224

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:33:17

[Continuing Flag](#)

---

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 20:25:54

---

US3172224

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:33:17

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:55:08
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:45:57
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 21:05:44

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:12:33
User entered 'USA-US118-2021-mRNA-1273-P301000004'	System	01 Feb 2021 13:12:30
User entered 'New'	(b) (4), (b) (6)	01 Feb 2021 13:12:30

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Chest and respiratory tract injuries NEC, PT: Traumatic haemothorax, LLT: Hemopneumothorax - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 11:09:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Apr 2021 11:09:53
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Chest and respiratory tract injuries NEC, PT: Traumatic haemothorax, LLT: Traumatic pneumohemothorax - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Mar 2021 21:30:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Mar 2021 21:30:18
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Chest and respiratory tract injuries NEC, PT: Traumatic haemothorax, LLT: Hemopneumothorax - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 19:21:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Feb 2021 19:21:36
Data point term sent to Coder	System	29 Jan 2021 19:53:19
User entered 'Hemopneumothorax - secondary to rib cage multiple fractures.'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '23 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Jan 2021 19:53:27
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:53:27
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Jan 2021 19:52:48
User entered '12:30'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 19:53:27
User entered '23 Jan 2021 12:30'	System	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '27 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	29 Jan 2021 19:53:27
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:53:27
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	29 Jan 2021 19:52:48
User entered '07:00'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 19:53:27
User entered '27 Jan 2021 07:00'	System	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:33:28
Query 'Per source, grade 3.' canceled (Site from CRA).	(b) (4), (b) (6)	30 Apr 2021 20:33:25
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:48
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User opened query 'Per source, grade 3.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 16:25:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	29 Jan 2021 19:53:27
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	29 Jan 2021 19:52:48
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		29 Jan 2021 20:38:41
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		29 Jan 2021 20:38:41
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	29 Jan 2021 19:53:27
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Jan 2021 19:53:27
User entered '0'	(b) (4) Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '23 Jan 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Jan 2021 19:54:18
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	29 Jan 2021 19:52:48
	(b) (4)	

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '27 Jan 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Jan 2021 19:54:18
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	29 Jan 2021 19:52:48
	(b) (4)	

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Jan 2021 20:38:41
User entered empty.	Jessie Downs (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 06:45:28
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'pending' (Site from DM).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:49:58
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:28:01
User entered 'I'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 18:27:08
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 18:26:56
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'Pending medical records.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 21:44:00
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'No results are available' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	03 Mar 2021 21:43:39
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:36:25
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:36:25

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:36:19
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:36:19
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:50:27
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:50:11
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:13:25
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:13:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Hemopneumothorax secondary to right rib cage multiple fractures due to a motor vehicle accident, requiring hospitalization and thoracotomy. Discharged home, stable and recovered from Hemopneumothorax (Acute / traumatic).'	Jessie Downs (b) (4)	29 Jan 2021 19:52:48

US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 19:52:48

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US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 19:52:48

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US3172224

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:33:17

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 20:38:41

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US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:10
User entered 'USA-US118-2021-mRNA-1273-P301000004'	(b) (4), (b) (6)	01 Feb 2021 13:12:50

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Thoracic cage fractures and dislocations, PT: Rib fracture, LLT: Fractured ribs - version MedDRA\23.0.	Coder Import (b) (4)	14 Apr 2021 18:50:59
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Apr 2021 18:50:59
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Thoracic cage fractures and dislocations, PT: Rib fracture, LLT: Fracture rib - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 21:49:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	08 Apr 2021 21:49:07
User closed query 'PV Query: The event term 'Right rib cage multiple fractures - secondary to car accident' contains multiple event terms. Please consider reporting 'car accident' as a separate event.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:26:21
Data point term sent to Coder	System	08 Apr 2021 13:32:06
Query 'PV Query: The event term 'Right rib cage multiple fractures - secondary to car accident' contains multiple event terms. Please consider reporting 'car accident' as a separate event.' answered with 'Data was updated.' (Site from Safety).	Jessie Downs (b) (4)	08 Apr 2021 13:32:05
Coding entries removed.	Jessie Downs (b) (4)	08 Apr 2021 13:31:42
User entered 'RIGHT RIB CAGE MULTIPLE FRACTURES' reason for change: Data Entry Error	Jessie Downs (b) (4)	08 Apr 2021 13:31:42
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Fractures and dislocations NEC, PT: Traumatic fracture, LLT: Traumatic fracture - version MedDRA\23.0.	Coder Import (b) (4)	10 Mar 2021 12:10:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Mar 2021 12:10:50

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The event term 'Right rib cage multiple fractures - secondary to car accident' contains multiple event terms. Please consider reporting 'car accident' as a separate event.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:37:16
User closed query 'PV Query: The event term 'Right rib cage multiple fractures - secondary to car accident' contains multiple event terms. Please consider reporting 'car accident' as a separate event.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:37:16
Query 'PV Query: The event term 'Right rib cage multiple fractures - secondary to car accident' contains multiple event terms. Please consider reporting 'car accident' as a separate event.' answered with 'data confirmed as entered.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:51:05
User opened query 'PV Query: The event term 'Right rib cage multiple fractures - secondary to car accident' contains multiple event terms. Please consider reporting 'car accident' as a separate event.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:12:14
Data point term sent to Coder	System	29 Jan 2021 20:02:53
User entered 'Right rib cage multiple fractures - secondary to car accident'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '23 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Jan 2021 20:11:04
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:11:04
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Jan 2021 20:02:31
User entered '12:30'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:11:04
User entered '23 Jan 2021 12:30'	System	29 Jan 2021 20:02:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:26:29
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date added.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	08 Apr 2021 13:32:55
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	07 Apr 2021 16:36:59
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 19:07:44
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 14:26:36
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'end date added.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	08 Apr 2021 13:33:15
User entered '1 Mar 2021' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	07 Apr 2021 16:36:59
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:37:37
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:37:37
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:51:18
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:08:44
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[AE End Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:02:31

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US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	29 Jan 2021 20:11:04
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	29 Jan 2021 20:02:31
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		29 Jan 2021 20:38:54
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		29 Jan 2021 20:38:54
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		29 Jan 2021 20:11:04
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		29 Jan 2021 20:11:04
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	29 Jan 2021 20:11:04
User entered '1' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Jan 2021 20:11:04
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4) System	29 Jan 2021 20:02:31
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '23 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User closed query 'PVQuery: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:38:58
Query 'PVQuery: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:51:33
User opened query 'PVQuery: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:12:25
User entered '27 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	29 Jan 2021 20:38:54
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	29 Jan 2021 20:02:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '1'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 06:46:18
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'pending' (Site from DM).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:51:47
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:28:11
User entered 'I'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 12:30:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	07 Apr 2021 16:36:59
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:39:22
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:39:22
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:52:00
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:09:09
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:43
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:39:29
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:39:29
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:39:07
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 19:39:02
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:52:31

US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'pending' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 21:52:14
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:10:10
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 15:09:17
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	29 Jan 2021 20:11:04
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	29 Jan 2021 20:11:04
User entered 'Right rib cage multiple fractures secondary to a motor vehicle accident on 1/23/2021 requiring hospitalization due to multiple trauma and Hemopneumothorax resolved with thoracostomy (chest tube) multiple abrasions right knee, both elbow, abdomen, hips, and forehead without clinically significance. He was discharged home on 1/27/2021 on a stable condition with oral meds for pain and swelling. Will monitor.' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:11:04
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	29 Jan 2021 20:02:31
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:02:31

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 20:02:31

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US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 20:02:31

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US3172224

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:33:17

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 20:38:54

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US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Skin injuries NEC, PT: Skin abrasion, LLT: Skin abrasion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Apr 2021 14:45:54
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 14:45:54
Data point term sent to Coder	System	08 Apr 2021 13:35:12
User closed query 'CDM Coding, please split the term (MULTIPLE SKIN ABRASIONS - SECONDARY TO A CAR ACCIDENT) into separate records, as 'MULTIPLE SKIN ABRASIONS' and 'CAR ACCIDENT' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).	System	08 Apr 2021 13:34:58
Query 'CDM Coding, please split the term (MULTIPLE SKIN ABRASIONS - SECONDARY TO A CAR ACCIDENT) into separate records, as 'MULTIPLE SKIN ABRASIONS' and 'CAR ACCIDENT' reporting each term separately with all relevant information e.g. start and stop dates etc. ' answered with 'Data was updated.' (Site from System).	Jessie Downs (b) (4) (b) (4)	08 Apr 2021 13:34:58
User entered 'MULTIPLE SKIN ABRASIONS' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	08 Apr 2021 13:34:24
Query 'Requery, Please separate the accident from the Injury. 1 per line' canceled (Site from Coder).	(b) (4), (b) (6)	30 Mar 2021 14:25:41
User opened query 'CDM Coding, please split the term (MULTIPLE SKIN ABRASIONS - SECONDARY TO A CAR ACCIDENT) into separate records, as 'MULTIPLE SKIN ABRASIONS' and 'CAR ACCIDENT' reporting each term separately with all relevant information e.g. start and stop dates etc. ' (Site from System).	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:20:00
User opened query 'Requery, Please separate the accident from the Injury. 1 per line' (Site from Coder).	(b) (4), (b) (6)	28 Feb 2021 13:10:55

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'For coding purposes, please split MULTIPLE SKIN ABRASIONS - SECONDARY TO A CAR ACCIDENT into separate entries. 1.  MULTIPLE SKIN ABRASIONS - [SECONDARY TO A CAR ACCIDENT] and 2. CAR ACCIDENT' (Site from Coder).	(b) (4), (b) (6)	28 Feb 2021 13:10:55
Query 'For coding purposes, please split MULTIPLE SKIN ABRASIONS - SECONDARY TO A CAR ACCIDENT into separate entries. 1. MULTIPLE SKIN ABRASIONS - [SECONDARY TO A CAR ACCIDENT] and 2. CAR ACCIDENT' answered with 'data confirmed as entered.' (Site from Coder).	Jessie Downs (b) (4)	26 Feb 2021 21:53:03
User opened query 'For coding purposes, please split MULTIPLE SKIN ABRASIONS - SECONDARY TO A CAR ACCIDENT into separate entries. 1. MULTIPLE SKIN ABRASIONS - [SECONDARY TO A CAR ACCIDENT] and 2. CAR ACCIDENT' (Site from Coder).	(b) (4), (b) (6)	02 Feb 2021 19:14:41
Data point term sent to Coder	System	29 Jan 2021 20:17:16
User entered 'Multiple skin abrasions - secondary to a car accident'	Jessie Downs (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '23 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Jan 2021 20:16:58
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	29 Jan 2021 20:16:58
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	29 Jan 2021 20:16:50
User entered '12:30'	Jessie Downs (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:16:58
User entered '23 Jan 2021 12:30'	System	29 Jan 2021 20:16:50

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 16:25:51
User entered 'Yes (Y)'	Jessie Downs (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '03 Mar 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 16:25:51
User entered empty.	(b) (4)	
	Jessie Downs (b) (4)	29 Jan 2021 20:16:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Not Related (NOT RELATED)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Not Applicable (NOT APPLICABLE)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '1'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:25:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:26:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:16:50

US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '0'	System	29 Jan 2021 20:16:50

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US3172224

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:33:17

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	29 Jan 2021 20:16:50

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US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:33:17

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:55:08
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:19

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:17:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:17:13
Data point term sent to Coder User entered 'IBUPROFEN'	System Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:16 19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'BACK PAIN'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '600'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
	(b) (4)	
User entered 'once daily (QD)'	Mariete Rendon (b) (4)	19 Aug 2020 21:15:55
	(b) (4)	

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4)	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4)	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:41:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 21:15:55
User entered 'UN UNK 1995'	Mariete Rendon (b) (4)	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 18:59:55
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 18:59:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 18:59:55
User entered '19 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 18:59:55
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User entered '1'	System	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User entered '1'	System	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:03:28
User entered '804 (804)'	System	19 Aug 2020 21:15:55

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:18:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 21:18:15
Data point term sent to Coder	System	19 Aug 2020 21:17:17
User entered 'FAMOTIDINE'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'HEARTBURN'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '10'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'as needed (PRN)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
	(b) (4)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:41:05
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 21:16:32
User entered 'UN UNK 2010'	Mariete Rendon (b) (4)	19 Aug 2020 21:16:32
	(b) (4)	

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	19 Aug 2020 21:16:32

US3172224

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:33:17**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:16:32

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US3172224

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:33:17**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:16:32

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US3172224

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:33:17**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 21:16:32

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US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med IBUPROFEN, #1 within this timeframe (UN UNK 1995 - ONGOING). Please consider updating dates so there is no overlap or delete if this is a duplicate. Update Con Med eCRF as appropriate. Otherwise, provide a comment.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 16:59:49
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med IBUPROFEN, #1 within this timeframe (UN UNK 1995 - ONGOING). Please consider updating dates so there is no overlap or delete if this is a duplicate. Update Con Med eCRF as appropriate. Otherwise, provide a comment.' answered with 'Data was updated ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 20:43:04
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with Con Med IBUPROFEN, #1 within this timeframe (UN UNK 1995 - ONGOING). Please consider updating dates so there is no overlap or delete if this is a duplicate. Update Con Med eCRF as appropriate. Otherwise, provide a comment.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 19:34:45
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 09:28:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 09:28:43
Data point term sent to Coder	System	25 Sep 2020 17:19:23
User entered 'Ibuprofen'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'historical back pain'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '600'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System). Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	16 Oct 2020 20:43:55
User entered 'unknown (UNKNOWN)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 20:43:55
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System). User entered 'once (ONCE)'	System	16 Oct 2020 20:42:46
	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'UN UNK 1995' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 20:42:46
User entered '22 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 18:59:16
User entered '16 Oct 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 18:59:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '22 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User entered empty.	System	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User entered empty.	System	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:58
User entered empty.	System	25 Sep 2020 17:18:26

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 15:37:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 15:37:29
Data point term sent to Coder	System	29 Jan 2021 20:24:21
User entered 'oxycodone'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 20:30:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 20:30:03
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:30:03
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 20:23:35
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'right rib cage pain'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '10'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'every 6 hours'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '23 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
	(b) (4)	
User entered '27 Jan 2021'	Jessie Downs (b) (4)	29 Jan 2021 20:23:35
	(b) (4)	

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User entered empty.	System	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User entered empty.	System	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:31
User entered empty.	System	29 Jan 2021 20:23:35

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: KETOROLAC TROMETHAMINE, PRODUCTSYNONYM: TORADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 15:43:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 15:43:29
Data point term sent to Coder	System	29 Jan 2021 20:27:25
User entered 'toradol'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 20:26:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jan 2021 20:26:56
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jan 2021 20:26:31
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'right rib cage pain'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '15'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
	(b) (4)	
User entered 'every 6 hours'	Jessie Downs (b) (4)	29 Jan 2021 20:26:31
	(b) (4)	

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '23 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '27 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User entered empty.	System	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User entered empty.	System	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:04:33
User entered empty.	System	29 Jan 2021 20:26:31

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 13:03:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Feb 2021 13:03:44
Data point term sent to Coder	System	29 Jan 2021 20:29:31
User entered 'tovenox'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'right rib cage pain'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '40'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
User entered 'every 12 hours'	Jessie Downs (b) (4)	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4)	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '23 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
	(b) (4)	
User entered '27 Jan 2021'	Jessie Downs (b) (4)	29 Jan 2021 20:28:32
	(b) (4)	

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User entered empty.	System	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User entered empty.	System	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:19
User entered empty.	System	29 Jan 2021 20:28:32

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:33:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:33:23
Data point term sent to Coder	System	29 Jan 2021 20:30:33
User entered 'gabapentin'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
	(b) (4)	
User entered 'right rib cage pain'	Jessie Downs (b) (4)	29 Jan 2021 20:29:33
	(b) (4)	

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '300'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'every 8 hours'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '23 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 18:58:18
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	22 Mar 2021 18:58:18
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:29:45
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:25:33
Signature has been broken.	Jessie Downs (b) (4)	22 Mar 2021 18:58:18
User entered '15 Mar 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	22 Mar 2021 18:58:18
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		29 Jan 2021 20:29:45
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		29 Jan 2021 20:29:33
User entered empty.	Jessie Downs (b) (4)	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User entered empty.	System	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User entered empty.	System	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:33:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:05:21
User entered empty.	System	29 Jan 2021 20:29:33

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:42:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 21:42:23
Data point term sent to Coder	System	29 Jan 2021 20:32:34
User entered 'ibuprofen'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'right rib cage pain - fractures'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '600'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'every 6 hours'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '23 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:31:47

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:33:17

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:31:47

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US3172224

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:33:17**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:31:47

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US3172224

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:33:17**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:31:47

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US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
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.	Coder Import (b) (4) (b) (4)	29 Jan 2021 20:34:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Jan 2021 20:34:23
Data point term sent to Coder	System	29 Jan 2021 20:33:34
User entered 'tylenol'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'right rib cage pain - fractures'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '500'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'every 6 hours'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '23 Jan 2021'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '0'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered empty.	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	29 Jan 2021 20:32:43

US3172224

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:33:17**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:32:43

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US3172224

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:33:17**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:32:43

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US3172224

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:33:17**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	29 Jan 2021 20:32:43

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US3172224

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:33:17

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	02 Sep 2020 21:06:09

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'USA-US118-2021-MRNA-1273-P301000004'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'Yes (Y)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'Yes (Y)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'Mark'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'Kutner'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'FL'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 14:28:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'US'	System	01 Feb 2021 13:13:49

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Apr 2021 14:29:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
	(b) (4)	
User entered '1'	System	01 Feb 2021 13:13:49

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'USA-US118-2021-MRNA-1273-P301000004'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'Yes (Y)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'Yes (Y)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'Mark'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'Kutner'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'FL'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 14:28:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'US'	System	01 Feb 2021 13:13:49

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Apr 2021 14:29:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
	(b) (4)	
User entered '1'	System	01 Feb 2021 13:13:49

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:33:17

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '01/Feb/2021 13:13'	System	01 Feb 2021 13:13:49

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:33:17

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 14:28:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered '1'	(b) (4), (b) (6)	01 Feb 2021 13:13:49

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'USA-US118-2021-MRNA-1273-P301000004'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'Yes (Y)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'Yes (Y)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

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Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'No (N)'	System	01 Feb 2021 13:12:30

US3172224

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Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'Mark'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'Kutner'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
Reviewed for Safety.	(b) (4), (b) (6)	01 Feb 2021 13:13:30
User entered 'FL'	System	01 Feb 2021 13:12:30

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
Reviewed for Safety.	(b) (4), (b) (6)	08 Apr 2021 14:28:54
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 13:11:39
User entered 'US'	System	01 Feb 2021 13:13:49

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 15:33:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Apr 2021 14:29:11
User signature succeeded.	Mark Kutner (b) (4)	17 Feb 2021 13:11:39
	(b) (4)	
User entered '1'	System	01 Feb 2021 13:13:49

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:33:17

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User entered '08/Apr/2021 10:29'	System	08 Apr 2021 14:29:11

US3172224

Folder: SAE USA-US118-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:33:17

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:25:33
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:23:53
User entered '1'	(b) (4), (b) (6)	08 Apr 2021 14:29:11