

US3522274 (Prod: Henry Ford Health System)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:58:52

All time stamps listed in this document are displayed in GMT

US3522274

**Form: Participant Creation**

**Data signed:** (b) (4) 05 Mar 2021 15:43:52

**Generated On: 10 Jun 2021 07:58:52**

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[Participant ID](#)

US3522274

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

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US3522274

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:43:53

Generated On: 10 Jun 2021 07:58:52

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Was this visit performed? Yes   
No

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Visit date (dd MMM yyyy) 21 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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US3522274

Folder: Screening

Form: Demographics

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

Date of Birth (MMM yyyy)	(b) (6) 1948
Age	72
Age Units	YEARS
Age (Derived)	72
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3522274

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

Date of Informed Consent (*dd MMM yyyy*) 21 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

US3522274

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

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Did the participant meet all eligibility criteria?

Yes

No

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US3522274

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 05 Mar 2021 15:43:53

Generated On: 10 Jun 2021 07:58:52

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Were any significant conditions reported?

Yes

No

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US3522274

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Apr 2021 11:37:42

Generated On: 10 Jun 2021 07:58:52

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



US3522274

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Apr 2021 11:37:42

Generated On: 10 Jun 2021 07:58:52

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

US3522274

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Apr 2021 11:37:42

Generated On: 10 Jun 2021 07:58:52

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

US3522274

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Apr 2021 11:37:42

Generated On: 10 Jun 2021 07:58:52

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

US3522274

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Apr 2021 11:37:42

Generated On: 10 Jun 2021 07:58:52

Condition	HISTORY OF EXERTIONAL CHEST PAIN
Start date (dd MMM yyyy)	
Start date completely unknown	True
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

US3522274

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 05 Mar 2021 15:43:53

Generated On: 10 Jun 2021 07:58:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	21 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	09:59 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 09:59
Height ( <i>xxx.x</i> )	67 in
Weight ( <i>xxx.x</i> )	158 lb
BMI ( <i>xxx.x</i> )	24.79804 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	99.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	65 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	51 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:43:53

Generated On: 10 Jun 2021 07:58:52

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Was the physical examination performed?

Yes

No

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Date of examination (dd MMM yyyy)

21 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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US3522274

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 15:43:53

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**Occupational Risk**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes  No

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes  No

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes  No

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes  No

**Warehouse shipping and fulfillment centers** and jobs (e.g., Amazon facilities) Yes  No

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes  No

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes  No

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes  No

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes  No

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes  No

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes  No

**Other** Yes  No

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**Specify** RETIRED

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 05 Mar 2021 15:43:53

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

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Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 26 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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US3522274

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

What was the date of randomization? (dd MMM yyyy) 26 AUG 2020

What was the participant's randomization number? 188351

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

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

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

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

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

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

Liver Disease Yes  No

Human Immunodeficiency Virus (HIV) infection Yes  No

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

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Height	ND - Not Done
Weight	ND - Not Done

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US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	09:45 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 09:45
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	52 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

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> )	26 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:10 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:10
Temperature ( <i>xxx.x</i> )	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	49 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	52 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

26 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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US3522274

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

Was study treatment given? Yes  No

If No, reason not given

Participant declined due to Adverse Event

Physician withheld dose due to Adverse Event

Death

Lost To Follow-Up

Physician Decision

Pregnancy

Protocol Deviation

Study Terminated by Sponsor

Withdrawal of Consent by Participant

Confirmed COVID-19

Other

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 26 AUG 2020

What was the treatment time? (00:00-23:59) 10:40 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 10:40

Which arm was used to give treatment? Left Arm  Right Arm

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

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Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	26 AUG 2020
Collection time ( <i>00:00-23:59</i> )	09:51 (24 HR)
Collection date and time (derived)	26 AUG 2020 09:51

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

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Collection date ( <i>dd MMM yyyy</i> )			26 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	09:58	26 AUG 2020 09:58
Nasopharyngeal Swab 2	No		

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US3522274

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 97.1 °F

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

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

PC Time Stamp 26 AUG 2020 11:12

PC Open Date & Time 26 AUG 2020 11:00

PC Close Date & Time 26 AUG 2020 13:30

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**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 97.4 °F

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

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

PC Time Stamp	26 AUG 2020 16:12
PC Open Date & Time	26 AUG 2020 14:25
PC Close Date & Time	27 AUG 2020 11:59

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**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	98.6 °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	27 AUG 2020 19:48
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**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	97.5 °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	28 AUG 2020 12:02
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**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	29 AUG 2020 15:04
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 98.1 °F

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

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

PC Time Stamp 30 AUG 2020 14:20

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59



US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**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	98.1 °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	31 AUG 2020 20:29
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

---

**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	99.1 °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	01 SEP 2020 19:25
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

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

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

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

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

- Yes
- No

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

- Yes
- No

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

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

PC Time Stamp

26 AUG 2020 11:00

PC Open Date & Time

26 AUG 2020 11:00

PC Close Date & Time

26 AUG 2020 13:30

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

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

Yes

No

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

Yes

No

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

Please select one response below

None

Does not interfere with activity

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

Any use of prescription pain  
reliever or prevents daily activity

PC Time Stamp

26 AUG 2020 16:14

PC Open Date & Time

26 AUG 2020 14:25

PC Close Date & Time

27 AUG 2020 11:59

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**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	27 AUG 2020 19:48
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**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

28 AUG 2020 12:01

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**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

29 AUG 2020 15:04

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**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	30 AUG 2020 14:19
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59



US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**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

31 AUG 2020 20:29

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**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

01 SEP 2020 19:26

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

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

No

Yes

---

PC Time stamp	26 AUG 2020 11:13
PC Open Date & Time	26 AUG 2020 11:00
PC Close Date & Time	26 AUG 2020 13:30

---

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

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

No   
Yes

---

PC Time stamp	26 AUG 2020 16:13
PC Open Date & Time	26 AUG 2020 14:25
PC Close Date & Time	27 AUG 2020 11:59

---

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

---

	Yes <input type="checkbox"/>
PC Time stamp	27 AUG 2020 19:49
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

---



US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

---

Yes

---

PC Time stamp	28 AUG 2020 12:02
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

---

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

---

	Yes <input type="checkbox"/>
PC Time stamp	29 AUG 2020 15:04
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

---

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

---

	Yes <input type="checkbox"/>
PC Time stamp	30 AUG 2020 14:20
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

---

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

---

	Yes <input type="checkbox"/>
PC Time stamp	31 AUG 2020 20:30
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

---



US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

---

	Yes <input type="checkbox"/>
PC Time stamp	01 SEP 2020 19:26
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

---

US3522274

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

EDIARY REVIEWED. MILD  
FATIGUE REPORTED ON DAYS 2  
& 5 WITH MILD MUSCLE/JOINT  
ACHES ALSO OCCURRING ON  
DAY 5. SYMPTOMS DID NOT  
INTERFERE WITH DAILY  
ACTIVITIES AND RESOLVED  
WITHOUT  
INTERVENTION/MEDICATION

US3522274

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

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

---

*If Contact Not Made, please provide Comments*

US3522274

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:37:04

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

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

---

*If Contact Not Made, please provide Comments*

US3522274

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3522274

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 23 SEP 2020

---

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

---

Folder OID VISIT2

---

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

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> )	23 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	12:00 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 12:00
Temperature ( <i>xxx.x</i> )	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	63 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	67 mmHg
Diastolic Blood Pressure units	MMHG

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

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> )	23 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	12:50 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 12:50
Temperature ( <i>xxx.x</i> )	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	62 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	21 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> )	56 mmHg
Diastolic Blood Pressure units	MMHG

US3522274

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

23 SEP 2020

---

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

---

US3522274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

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) 23 SEP 2020

What was the treatment time? (00:00-23:59) 12:20 (24 HR)

Treatment Date and Time (derived) 23 SEP 2020 12:20

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

US3522274

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 23 SEP 2020

---

Collection time (*00:00-23:59*) 12:10 (24 HR)

---

Collection date and time (derived) 23 SEP 2020 12:10

---

US3522274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Collection date ( <i>dd MMM yyyy</i> )			23 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	12:15	23 SEP 2020 12:15
Nasopharyngeal Swab 2	No		

---

US3522274

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1



US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp 23 SEP 2020 12:47

PC Open Date & Time 23 SEP 2020 12:40

PC Close Date & Time 23 SEP 2020 15:10

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 98.2 °F

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

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

PC Time Stamp 23 SEP 2020 20:53  
PC Open Date & Time 23 SEP 2020 16:05  
PC Close Date & Time 24 SEP 2020 11:59

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**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	98.1 °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 SEP 2020 21:18
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**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	98.1 °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 SEP 2020 22:15
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**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	98.4 °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	26 SEP 2020 20:12
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**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	98.2 °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	27 SEP 2020 23:29
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**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	97.7 °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	29 SEP 2020 07:56
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**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	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	29 SEP 2020 22:16
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59



US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**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

23 SEP 2020 14:55

PC Open Date & Time

23 SEP 2020 12:40

PC Close Date & Time

23 SEP 2020 15:10

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**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

23 SEP 2020 20:54

PC Open Date & Time

23 SEP 2020 16:05

PC Close Date & Time

24 SEP 2020 11:59

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**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	24 SEP 2020 21:19
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**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

25 SEP 2020 22:15

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**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

26 SEP 2020 20:13

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**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

27 SEP 2020 23:29

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**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

29 SEP 2020 07:57

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**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	29 SEP 2020 22:16
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59



US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

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

No   
Yes

---

PC Time stamp	23 SEP 2020 14:56
PC Open Date & Time	23 SEP 2020 12:40
PC Close Date & Time	23 SEP 2020 15:10

---

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

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

No

Yes

---

PC Time stamp	23 SEP 2020 20:54
PC Open Date & Time	23 SEP 2020 16:05
PC Close Date & Time	24 SEP 2020 11:59

---

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

---

	Yes <input type="checkbox"/>
PC Time stamp	24 SEP 2020 21:19
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

---

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

---

	Yes <input type="checkbox"/>
PC Time stamp	25 SEP 2020 22:16
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

---



US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

---

	Yes <input type="checkbox"/>
PC Time stamp	26 SEP 2020 20:13
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

---

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

---

	Yes <input type="checkbox"/>
PC Time stamp	27 SEP 2020 23:30
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

---

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

---

	Yes <input type="checkbox"/>
PC Time stamp	29 SEP 2020 07:57
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

---

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

---

	Yes <input type="checkbox"/>
PC Time stamp	29 SEP 2020 22:17
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

---



US3522274

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments CLINCARD NOT ACTIVATED.  
SAYS WRONG BIRTHDAY. NO  
ONGOING AES, NO NEW  
ILLNESS OR HOSPITAL VISITS;  
NO CHANGES IN HEALTH  
STATUS, MEDICATIONS,  
COVID-19 EXPOSURE.

---

*If Contact Not Made, please provide Comments*

US3522274

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Was Contact Attempted? Yes  No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 7 OCT 2020

---

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

---

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

*If Contact Not Made, please provide Comments*

---

US3522274

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 15 OCT 2020

---

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

---

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

---

US3522274

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 28 OCT 2020

---

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

---

Folder OID VISIT3

---

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	28 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	12:00 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 12:00
Temperature ( <i>xxx.x</i> )	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	67 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	57 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3522274

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

28 OCT 2020

---

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

---

US3522274

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	28 OCT 2020
Collection time ( <i>00:00-23:59</i> )	12:15 (24 HR)
Collection date and time (derived)	28 OCT 2020 12:15

---

US3522274

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 18:37:05

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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	26 OCT 2020 07:55:21
Patient Cloud Open Date & Time	26 OCT 2020 00:01
Patient Cloud Close Date & Time	30 OCT 2020 23:59

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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	04 NOV 2020 12:00:56
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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 10 NOV 2020 20:34:39

Patient Cloud Open Date & Time 09 NOV 2020 00:01

Patient Cloud Close Date & Time 13 NOV 2020 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 89

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

No

Yes

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

No

Yes

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

Date and time of submission 21 NOV 2020 11:28:23

Patient Cloud Open Date & Time 20 NOV 2020 00:01

Patient Cloud Close Date & Time 24 NOV 2020 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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	29 NOV 2020 07:50:48
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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 04 DEC 2020 13:49:24

Patient Cloud Open Date & Time 04 DEC 2020 00:01

Patient Cloud Close Date & Time 08 DEC 2020 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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	11 DEC 2020 07:39:01
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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	18 DEC 2020 08:02:37
Patient Cloud Open Date & Time	18 DEC 2020 00:01
Patient Cloud Close Date & Time	22 DEC 2020 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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	25 DEC 2020 08:43:55
Patient Cloud Open Date & Time	25 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 08:41:34
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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 <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	08 JAN 2021 08:24:56
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 07:58:34
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 152

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

No

Yes

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

No

Yes

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

Date and time of submission 22 JAN 2021 08:20:26

Patient Cloud Open Date & Time 22 JAN 2021 00:01

Patient Cloud Close Date & Time 26 JAN 2021 23:59



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 159

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

No

Yes

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

No

Yes

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

Date and time of submission 29 JAN 2021 08:24:02

Patient Cloud Open Date & Time 29 JAN 2021 00:01

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

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 09:09:26
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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 14 FEB 2021 12:25:02

Patient Cloud Open Date & Time 12 FEB 2021 00:01

Patient Cloud Close Date & Time 16 FEB 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 180

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

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 187

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

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 FEB 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 MAR 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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



US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#) 09 MAR 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	16 MAR 2021 12:59:21
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 208

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

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 MAR 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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 <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	30 MAR 2021 11:21:32
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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 02 APR 2021 08:28:28

Patient Cloud Open Date & Time 02 APR 2021 00:01

Patient Cloud Close Date & Time 06 APR 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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	09 APR 2021 08:39:27
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

<b>TIMEPOINT</b>	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	16 APR 2021 07:32:53
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 12:04:53
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 250

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

No

Yes

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

No

Yes

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

Date and time of submission 30 APR 2021 09:19:18

Patient Cloud Open Date & Time 30 APR 2021 00:01

Patient Cloud Close Date & Time 04 MAY 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 257

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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°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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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](#)

09 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

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20 JUL 2021 23:59



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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](#)

30 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#) 10 AUG 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#) 17 AUG 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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20 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 AUG 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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°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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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](#)

03 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#) 28 SEP 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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°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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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26 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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](#)

03 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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>	10 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 DEC 2021 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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Date and time of submission

<a href="#">Patient Cloud Open Date &amp; Time</a>	24 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 DEC 2021 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

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**Generated On: 10 Jun 2021 07:58:52**

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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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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°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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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22 FEB 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 MAR 2022 00:01

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

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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°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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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](#)

01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 APR 2022 00:01

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26 APR 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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](#)

20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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<a href="#">Patient Cloud Open Date &amp; Time</a>	27 MAY 2022 00:01
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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 JUN 2022 00:01

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07 JUN 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

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**Generated On: 10 Jun 2021 07:58:52**

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Date and time of submission

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10 JUN 2022 00:01

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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17 JUN 2022 00:01

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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

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

US3522274

**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](#) 24 JUN 2022 00:01

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

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**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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01 JUL 2022 00:01

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 JUL 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**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

US3522274

**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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**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°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

US3522274

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

**Form: Safety Follow Up Diary**

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Folder: New Safety Follow Up Diary (1)

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**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3522274

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

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02 AUG 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

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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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09 AUG 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

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Date and time of submission

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12 AUG 2022 00:01

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16 AUG 2022 23:59

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Generated On: 10 Jun 2021 07:58:52

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

Please contact your study clinic immediately. Click below to confirm that you have read this 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>	02 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 SEP 2022 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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°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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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](#)

09 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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](#)

16 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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](#)

23 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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°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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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](#)

30 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

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

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

Fatigue \_\_\_\_\_

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

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

Headache \_\_\_\_\_

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

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

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

Congestion \_\_\_\_\_

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

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2022 23:59

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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

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[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

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US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**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

US3522274

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

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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 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

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US3522274

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 07:58:52

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		16 MAR 2021 14:15:18

US3522274

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 19 NOV 2020

---

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

---

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

*If Contact Not Made, please provide Comments*



US3522274

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

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

*If Contact Not Made, please provide Comments*

US3522274

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments MERGED WITH OL VISIT

---

*If Contact Not Made, please provide Comments*

---

US3522274

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments DID NOT MAKE IT FOR OL  
DOSE2 APPOINTMENT AS HE  
HAD TO GO TO THE HOSPITAL  
YESTERDAY, 17 FEB 2021  
(UNIVERSITY OF MICHIGAN)  
FOR WORSENING CHEST PAIN  
(SINCE LAST WEEK) AND  
NEW-ONSET SOB

---

*If Contact Not Made, please provide Comments*

US3522274

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 11:56:25

Generated On: 10 Jun 2021 07:58:52

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 9 APR 2021

---

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

---

Folder OID VISIT4

---



US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 11:56:25

Generated On: 10 Jun 2021 07:58:52

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	9 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	11:14 (24 HR)
Vital Signs Date and Time (derived)	9 APR 2021 11:14
Temperature ( <i>xxx.x</i> )	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	65 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3522274

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 11:56:25

Generated On: 10 Jun 2021 07:58:52

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

9 APR 2021

---

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

---

US3522274

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 11:56:25

Generated On: 10 Jun 2021 07:58:52

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 9 APR 2021

---

Collection time (*00:00-23:59*) 11:25 (24 HR)

---

Collection date and time (derived) 9 APR 2021 11:25

---

US3522274

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 11:56:25

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 12:36:22

Generated On: 10 Jun 2021 07:58:52

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 22 APR 2021

---

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

---

Comments SEE SOURCE DOC FOR DETAILS

---

*If Contact Not Made, please provide Comments*

---

US3522274

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 12:36:22

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

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* \_\_\_\_\_

US3522274

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---



US3522274

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:58:52

---

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"/>

---

US3522274

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 07:58:52

---

Generate Next COVID-19 Assessment

Yes

No

---

US3522274

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 19 JAN 2021

---

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

---

Folder OID UNBLND\_DECIDE

---

US3522274

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

Form: Unblinding

Data signed: (b) (4) 19 Mar 2021 18:11:41

Generated On: 10 Jun 2021 07:58:52

Date of updated informed consent ( <i>dd MMM yyyy</i> )	19 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> )	19 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

US3522274

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Height

---

Weight

---

BMI (xxx.x)

---

US3522274

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

Height	
Weight	
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 JAN 2021
Time of assessment (00:00-23:59)	14:12 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 14:12
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

US3522274

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

Height	
Weight	
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 JAN 2021
Time of assessment (00:00-23:59)	14:53 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 14:53
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3522274

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

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

19 JAN 2021

---

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

---



US3522274

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

Form: Exposure

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

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 JAN 2021

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

Treatment Date and Time (derived) 19 JAN 2021 14:22

Which arm was used to give treatment? Left Arm   
Right Arm

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3522274

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 19 JAN 2021

---

Collection time (*00:00-23:59*) 14:16 (24 HR)

---

Collection date and time (derived) 19 JAN 2021 14:16

---

US3522274

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 19 JAN 2021

---

Collection time (*00:00 - 23:59*) 14:18

---

Collection Date and Time (derived) 19 JAN 2021 14:18

---

US3522274

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

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Was Contact Attempted? Yes  No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 26 JAN 2021

---

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

---

Comments REPORTS ARM SORENESS FOR 2  
DAYS WITH RESOLUTION,  
DENIES ANY OTHER AES. NO  
NEW ILLNESS OR HOSPITAL  
VISITS; NO CHANGES IN  
HEALTH STATUS,  
MEDICATIONS, COVID-19  
EXPOSURE OR PREGNANCY  
RISK

---

*If Contact Not Made, please provide Comments*

US3522274

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

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

---

US3522274

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 11:56:24

Generated On: 10 Jun 2021 07:58:52

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

---

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Apr 2021 11:56:25

Generated On: 10 Jun 2021 07:58:52

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> )	9 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	11:14 (24 HR)
Vital Signs Date and Time (derived)	9 APR 2021 11:14
Temperature ( <i>xxx.x</i> )	97.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	65 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	64 mmHg
Diastolic Blood Pressure units	MMHG



US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Apr 2021 11:56:25

Generated On: 10 Jun 2021 07:58:52

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> )	9 APR 2021
Time of assessment ( <i>00:00-23:59</i> )	11:57 (24 HR)
Vital Signs Date and Time (derived)	9 APR 2021 11:57
Temperature ( <i>xxx.x</i> )	98.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse ( <i>xxx</i> )	65 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	74 mmHg
Diastolic Blood Pressure units	MMHG

US3522274

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 11:56:24

Generated On: 10 Jun 2021 07:58:52

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

9 APR 2021

---

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

---

US3522274

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Apr 2021 11:56:24

Generated On: 10 Jun 2021 07:58:52

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) 9 APR 2021

What was the treatment time? (00:00-23:59) 11:27 (24 HR)

Treatment Date and Time (derived) 9 APR 2021 11:27

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

US3522274

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 11:56:24

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 16 APR 2021

---

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

---

Comments PARTICIPANT HAD MUSCLE  
*If Contact Not Made, please provide Comments* ACHES FOR 14 HOURS AFTER  
DOSE AND TOOK TYLENOL  
THAT EVENING 1000MG. NO  
ISSUES THE NEXT DAY.

---

US3522274

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3522274

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

---

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 \_\_\_\_\_

US3522274

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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)	_____



US3522274

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

---

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.*

---

US3522274

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

Was the sample collected? Yes   
No

Collection date (*dd MMM yyyy*) \_\_\_\_\_

Collection time (*00:00-23:59*) \_\_\_\_\_

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

US3522274

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

AEID	USA-US131-2021-MRNA-1273-P30 1000009
Adverse event	CORONARY ARTERY DISEASE
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)	10 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	23 MAR 2021
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	10

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

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 checked="" type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

---

FROM SAFETY CALL: DID NOT MAKE IT FOR OL DOSE2 APPOINTMENT AS HE HAD TO GO TO THE HOSPITAL FOR WORSENING CHEST PAIN (SINCE LAST WEEK) AND NEW-ONSET SOB. REPORTED GOING ON 17 FEB 2021 BUT HOSPITAL RECORDS INDICATE ARRIVAL THE NIGHT OF 16 FEB 2021. HE IS NOW WAITING FOR A CORONARY ARTERY BYPASS (MAJOR ARTERY BIFURCATION) TOMORROW (19 FEB 2021) OR ON SATURDAY (20 FEB 2021). HE HAS A HISTORY OF EXERTIONAL CHEST PAIN AND HIGH BLOOD PRESSURE, BUT DIDN'T THINK MUCH OF IT UNTIL LAST WEEK'S CHANGES. CHART CHECKED ON MARCH 11TH. PARTICIPANT IS STILL ADMITTED AT THIS TIME. PARTICIPANT POST CABG AND AORTIC VALVE REPLACEMENT. PATIENT FOUND TO HAVE PLEURAL EFFUSION AND HAD FLUID 300ML OF FLUID ASPIRATED UNDER ULTRASOUND GUIDANCE ON 3/10/21. RENAL LABS ARE ELEVATED AT THIS TIME. SOME ABNORMALITIES IN REGULAR DAILY BLOOD WORK. PARTICIPANT HAD NEGATIVE COVID SWAB ON 3/6/21. HAD IMAGING DONE ON 3/10/21 AND FOUND TO HAVE DEEP VEIN THROMBOSIS BILATERALLY IN SEVERAL VEINS.

---

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)	1

---

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EAB) (1725)

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US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

AEID USA-US131-2021-MRNA-1273-P30  
1000009

Adverse event NEW ONSET SHORTNESS OF BREATH

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) 17 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy)

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) 16 FEB 2021

Hospital Discharge Date (dd MMM yyyy) 23 MAR 2021

Admitted to ICU? Yes   
No   
Unknown

Number of Days in ICU 10

PRODUCTION RELEASE (v12.003 350 of 2275  
EAB) (1725)

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

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 checked="" type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	



US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

---

DID NOT MAKE IT FOR OL  
DOSE2 APPOINTMENT AS HE  
HAD TO GO TO THE HOSPITAL  
16 FEB 2021 (UNIVERSITY OF  
MICHIGAN) FOR WORSENING  
CHEST PAIN (SINCE LAST  
WEEK) AND NEW-ONSET SOB.  
HE IS NOW WAITING FOR A  
CORONARY ARTERY BYPASS  
(MAJOR ARTERY  
BIFURCATION) TOMORROW (19  
FEB 2021) OR ON SATURDAY (20  
FEB 2021). HE HAS A HISTORY  
OF EXERTIONAL CHEST PAIN  
AND HIGH BLOOD PRESSURE,  
BUT DIDN'T THINK MUCH OF IT  
UNTIL LAST WEEK'S CHANGES.

---

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)	1

---

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

AEID USA-US131-2021-MRNA-1273-P30  
1000009

Adverse event PLEURAL EFFUSION

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) 10 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy)

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) 16 FEB 2021

Hospital Discharge Date (dd MMM yyyy) 23 MAR 2021

Admitted to ICU? Yes   
No   
Unknown

Number of Days in ICU 10

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US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

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 checked="" type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PLEURAL EFFUSION DIAGNOSED ON 10 MAR 2021 WHILE IN THE HOSPITAL, ORIGINALLY WENT FOR SHORTNESS OF BREATH. NOT MAIN COMPLAINT AT THIS TIME PER RECORDS ABLE TO BE SEEN FOR 10 MAR 2021.
Serious Adverse Event Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

---

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	1

---

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

AEID USA-US131-2021-MRNA-1273-P30  
1000009

Adverse event BILATERAL DEEP VEIN  
THROMBOSIS

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) 10 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy)

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 True

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 16 FEB 2021

Hospital Discharge Date (dd MMM yyyy) 23 MAR 2021

Admitted to ICU? Yes   
No   
Unknown

Number of Days in ICU 10

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EAB) (1725)

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

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 checked="" type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative	

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

---

THE FOLLOWING RIGHT-SIDED  
VEINS REVEALED EVIDENCE  
OF ACUTE DEEP VENOUS  
THROMBOSIS (DVT): MID  
POSTERIOR TIBIAL VEIN  
(TOTALLY OCCLUDING);  
DISTAL POSTERIOR TIBIAL  
VEIN (TOTALLY OCCLUDING);  
PROXIMAL PERONEAL VEIN  
(TOTALLY OCCLUDING); MID  
PERONEAL VEIN (TOTALLY  
OCCLUDING); DISTAL  
PERONEAL VEIN (TOTALLY  
OCCLUDING); SOLEAL VEIN  
(TOTALLY OCCLUDING);  
· THE FOLLOWING  
RIGHT-SIDED VEINS REVEALED  
EVIDENCE OF ACUTE  
SUPERFICIAL THROMBOSIS:  
GREAT SAPHENOUS VEIN  
(PARTIALLY OCCLUDING) LESS  
THAN 5 CM;  
· THE FOLLOWING LEFT-SIDED  
VEINS REVEALED EVIDENCE  
OF ACUTE DEEP VENOUS  
THROMBOSIS (DVT): PROX  
PERONEAL VEIN (TOTALLY  
OCCLUDING); MID PERONEAL  
VEIN (TOTALLY OCCLUDING);  
DISTAL PERONEAL VEIN  
(TOTALLY OCCLUDING);  
SOLEAL VEIN (TOTALLY  
OCCLUDING);

---

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)	1

---

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 15:43:52

Generated On: 10 Jun 2021 07:58:52

---

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

Yes

No

---

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

---



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

Name of Medication LOSARTAN

Prophylaxis Yes   
No

Indication HYPERTENSION

Dose per administration 100

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

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) \_\_\_\_\_

Start date completely unknown  True

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 19 FEB 2021

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

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

Name of Medication MIRTAZAPINE

Prophylaxis Yes   
No

Indication ANXIETY AND DEPRESSION

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

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

---

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*) \_\_\_\_\_

---

Start date completely unknown True

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

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

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

Name of Medication TETRAHYDROCANNABINOL

Prophylaxis Yes   
No

Indication ANXIETY

Dose per administration 5

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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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

---

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*) \_\_\_\_\_

---

Start date completely unknown True

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

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

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

Name of Medication OMEPRAZOLE

Prophylaxis Yes   
No

Indication GERD

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

---

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*) \_\_\_\_\_

---

Start date completely unknown True

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

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



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

Name of Medication ASPIRIN

Prophylaxis Yes   
No

Indication CARDIOPROTECTIVE

Dose per administration 81

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

---

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*) 03 APR 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) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

Name of Medication FUROSEMIDE

Prophylaxis Yes   
No

Indication CARDIAC ISSUES

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

---

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*) 3 APR 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) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

Name of Medication LISINOPRIL

Prophylaxis Yes   
No

Indication HYPERTENSION

Dose per administration 2.5

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

---

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*) 3 APR 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) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

Name of Medication METOPROLOL TARTRATE

Prophylaxis Yes   
No

Indication HYPERTENSION

Dose per administration 12.5

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  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

---

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*) 3 APR 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) 2

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

Name of Medication MIRALAX

Prophylaxis Yes   
No

Indication PROPHYLAXIS FOR  
CONSTIPATION

Dose per administration 17

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

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

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

---

	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) 3 APR 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) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

Name of Medication WARFARIN

Prophylaxis Yes   
No

Indication CARDIAC ISSUES

Dose per administration 3

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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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

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*) 2 APR 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) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

Name of Medication FERROUS SULFATE

Prophylaxis Yes   
No

Indication PROPHYLACTIC ELECTROLYTE

Dose per administration 325

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

---

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*) 3 APR 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) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

Name of Medication MAGNESIUM OXIDE

Prophylaxis Yes   
No

Indication ELECTROLYTE PROPHYLAXIS

Dose per administration 400

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

---

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*) 3 APR 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) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

Name of Medication TYLENOL

Prophylaxis Yes   
No

Indication MYALGIA POST DOSE 2

Dose per administration 1000

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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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 19 Apr 2021 19:03:11

Generated On: 10 Jun 2021 07:58:52

---

Intramuscular	<input type="checkbox"/>
Respiratory (Inhalation)	<input type="checkbox"/>
Intralesional	<input type="checkbox"/>
Intraperitoneal	<input type="checkbox"/>
Nasal	<input type="checkbox"/>
Vaginal	<input type="checkbox"/>
Rectal	<input type="checkbox"/>
Intravenous	<input type="checkbox"/>
Intravenous Bolus	<input type="checkbox"/>
Intravenous Drip	<input type="checkbox"/>
Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (*dd MMM yyyy*) 09 APR 2021

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 09 APR 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

US3522274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Mar 2021 15:20:56

Generated On: 10 Jun 2021 07:58:52

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3522274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 12:36:22

Generated On: 10 Jun 2021 07:58:52

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
10 MAR 2021	THORACENTESIS	Adverse Event	
19 FEB 2021	CORONARY ARTERY BYPASS AND AORTIC VALVE REPLACEMENT	Adverse Event	
13 APR 2021	CHEST X-RAY	Adverse Event	

US3522274

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:58:52

---

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

---

US3522274

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:58:52

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

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 29 Apr 2021 22:45:32

Generated On: 10 Jun 2021 07:58:52

SAEID	USA-US131-2021-MRNA-1273-P30 1000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input 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	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 29 Apr 2021 22:45:32

Generated On: 10 Jun 2021 07:58:52

SAEID	USA-US131-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	04/MAR/2021 15:50
<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>	True



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 29 Apr 2021 22:45:32

Generated On: 10 Jun 2021 07:58:52

SAEID	USA-US131-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/MAR/2021 13:51
<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>	True

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 29 Apr 2021 22:45:32

Generated On: 10 Jun 2021 07:58:52

SAEID	USA-US131-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	16/MAR/2021 09:37
<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>	True

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 29 Apr 2021 22:45:32

Generated On: 10 Jun 2021 07:58:52

SAEID	USA-US131-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/MAR/2021 13:30
<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>	True

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Data signed: (b) (4) 29 Apr 2021 22:45:32

Generated On: 10 Jun 2021 07:58:52

SAEID	USA-US131-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	12/APR/2021 13:10
<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>	True

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Data signed: (b) (4) 29 Apr 2021 22:45:32

Generated On: 10 Jun 2021 07:58:52

SAEID	USA-US131-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	14/APR/2021 09:30
<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>	True

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (7)

Data signed: (b) (4) 29 Apr 2021 22:45:32

Generated On: 10 Jun 2021 07:58:52

SAEID	USA-US131-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	MARCUS
Investigator's Last Name	ZERVOS
Site Address: Street	2799 WEST GRAND BLVD
Site Address: City	DETROIT
Site Address: State	
Site Address: Postal Code	48202
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	7
Date of submission (Pre-filled from custom function)	29/APR/2021 15:23
<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>	True

Audit

US3522274 (Prod: Henry Ford Health System)

US3522274

**Form: Participant Creation**

**Generated On: 10 Jun 2021 07:58:52**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'US3522274'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 13:44:24



US3522274

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:54:32

US3522274

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '21 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 13:44:25

US3522274

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:54:32

US3522274

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'SCRN'	System	21 Aug 2020 13:54:32

US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered (b) (6) 1948'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 13:44:26

US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '72'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:54:49

US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'YEARS'	System	21 Aug 2020 13:54:49

US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered '72'	System	21 Aug 2020 13:55:02



US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:54:49

US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:54:49

US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:54:49

US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:54:49

US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:54:49

US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:54:49

US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:54:49

US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:54:49



US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:54:49

US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:54:49

US3522274

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:58:52

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:54:49

US3522274

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:52

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:55:02

US3522274

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'Aug 2020'	System	21 Aug 2020 13:55:02

US3522274

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered '2020'	System	21 Aug 2020 13:55:02

US3522274

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:52

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:55:02

US3522274

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:55:02



US3522274

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:52

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:55:02

US3522274

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:52

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:55:02

US3522274

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:52

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:55:02

US3522274

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:52

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	21 Aug 2020 13:44:25

US3522274

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:58:52

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered '1'	System	21 Aug 2020 13:55:07

US3522274

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:55:07

US3522274

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:58:52

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:55:13

US3522274

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 14:08:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 14:08:15
Data point term sent to Coder	System	21 Aug 2020 14:07:22
User entered 'Hypertension'	(b) (4), (b) (6)	21 Aug 2020 14:06:35



US3522274

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:06:35

US3522274

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:06:35

US3522274

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:06:35

US3522274

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:06:35

US3522274

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:06:35

US3522274

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	21 Aug 2020 14:06:35

US3522274

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	21 Aug 2020 14:06:35

US3522274

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	21 Aug 2020 14:06:35



US3522274

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	21 Aug 2020 14:06:35

US3522274

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User coded data point as SOC: Psychiatric disorders, HLT: Depressive disorders, PT: Depression, LLT: Anxiety depression - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 22:46:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 22:46:19
Data point term sent to Coder	System	21 Aug 2020 14:07:24
User entered 'Anxiety, Depression'	(b) (4), (b) (6)	21 Aug 2020 14:06:48

US3522274

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:06:48

US3522274

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:06:48

US3522274

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:06:48

US3522274

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:06:48

US3522274

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:06:48

US3522274

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	21 Aug 2020 14:06:48



US3522274

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	21 Aug 2020 14:06:48

US3522274

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	21 Aug 2020 14:06:48

US3522274

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	21 Aug 2020 14:06:48

US3522274

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 14:08:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 14:08:16
Data point term sent to Coder	System	21 Aug 2020 14:07:24
User entered 'GERD'	(b) (4), (b) (6)	21 Aug 2020 14:07:02

US3522274

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:07:02

US3522274

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:07:02

US3522274

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:07:02

US3522274

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:07:02



US3522274

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:07:02

US3522274

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	21 Aug 2020 14:07:02

US3522274

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	21 Aug 2020 14:07:02

US3522274

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	21 Aug 2020 14:07:02

US3522274

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	21 Aug 2020 14:07:02

US3522274

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:52

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User coded data point as SOC: Investigations, HLT: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Heart murmur - version MedDRA\23.0.	Coder Import (b) (4)	26 Aug 2020 13:51:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	26 Aug 2020 13:51:45
Data point term sent to Coder	System	26 Aug 2020 13:50:33
User entered 'Heart Murmur'	(b) (4), (b) (6)	26 Aug 2020 13:50:02

US3522274

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:50:02

US3522274

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:50:02



US3522274

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:50:02

US3522274

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:50:02

US3522274

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:50:02

US3522274

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	26 Aug 2020 13:50:02

US3522274

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	26 Aug 2020 13:50:02

US3522274

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	26 Aug 2020 13:50:02

US3522274

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	26 Aug 2020 13:50:02

US3522274

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:52

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:37:42
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain exertional - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 11:47:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Mar 2021 11:47:19
Data point term sent to Coder	System	29 Mar 2021 15:17:16
User closed query 'DM-Coding: for term HISTORY OF EXERTIONAL CHEST PAIN, Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain. Please update the reported term. ' (Site from System).	System	29 Mar 2021 15:16:26
Query 'DM-Coding: for term HISTORY OF EXERTIONAL CHEST PAIN, Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain. Please update the reported term. ' answered with 'Self reported, not diagnosed. Asked by DMs to add into medical history due to the AE. Current AE is cardiac related, but that does not mean this was as it was never investigated. Please confirm whether this should stay in or the previous request should be disregarded.' (Site from System).	Sharon Mathys (b) (4)	29 Mar 2021 15:16:26
User opened query 'DM-Coding: for term HISTORY OF EXERTIONAL CHEST PAIN, Please enter the type of Chest Pain e.g. cardiac, non-cardiac or musculoskeletal chest pain. Please update the reported term. ' (Site from System).	Coder Import (b) (4)	29 Mar 2021 14:32:01
Data point term sent to Coder	System	26 Mar 2021 13:00:47
User entered 'History of Exertional Chest Pain'	Sharon Mathys (b) (4)	26 Mar 2021 13:00:31



US3522274

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:37:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Mar 2021 13:00:31

US3522274

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:37:42
User entered '1'	Sharon Mathys (b) (4) (b) (4)	26 Mar 2021 13:00:31

US3522274

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:52

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:37:42
User entered 'Yes (Y)'	Sharon Mathys (b) (4) (b) (4)	26 Mar 2021 13:00:31

US3522274

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:37:42
User entered empty.	Sharon Mathys (b) (4) (b) (4)	26 Mar 2021 13:00:31

US3522274

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:52

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Apr 2021 11:37:42
User entered '0'	Sharon Mathys (b) (4) (b) (4)	26 Mar 2021 13:00:31

US3522274

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:52

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	26 Mar 2021 13:00:31

US3522274

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:52

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	26 Mar 2021 13:00:31

US3522274

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	26 Mar 2021 13:00:31



US3522274

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	26 Mar 2021 13:00:31

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:02:45

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:02:45

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '09:59'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:02:45

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered '21 Aug 2020 09:59'	System	21 Aug 2020 14:02:45

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '67' in	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:02:45
DataPoint set to visible.	System	21 Aug 2020 13:55:07

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '158' lb	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:02:45
DataPoint set to visible.	System	21 Aug 2020 13:55:07

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
Amendment Manager: User entered '24.79804'	System	17 Sep 2020 00:17:47
User entered '24.8'	System	21 Aug 2020 14:02:45
DataPoint set to visible.	System	21 Aug 2020 13:55:07



US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'kg/m2'	System	21 Aug 2020 14:02:45
DataPoint set to visible.	System	21 Aug 2020 13:55:07

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '99.0' F	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:02:45

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:02:45

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Temporal' reason for change: Data Entry Error	(b) (4)	05 Sep 2020 19:57:48
User entered 'Infrared'	Sharon Mathys (b) (4)	21 Aug 2020 14:02:45
	(b) (4)	

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '65'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:02:45

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'bpm'	System	21 Aug 2020 14:02:45

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '16'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:02:45

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'breaths/min'	System	21 Aug 2020 14:02:45



US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '149'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:02:45

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'mmHg'	System	21 Aug 2020 14:02:45

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 05:48:45
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Sharon Mathys (b) (4) (b) (4)	17 Sep 2020 15:49:19
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:17:47
User entered '51'	(b) (4), (b) (6)	21 Aug 2020 14:02:45

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'mmHg'	System	21 Aug 2020 14:02:45

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15

US3522274

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15

US3522274

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 14:03:06

US3522274

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	27 Aug 2020 13:47:28
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 13:39:47
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:03:06



US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04



US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Retired'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04



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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '1'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

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Folder: Screening

Form: Risk of Exposure

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**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:56:04

US3522274

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:39:47

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:39:47

US3522274

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:39:47



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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'VISIT1'	System	26 Aug 2020 13:39:47

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '26 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 13:45:18

US3522274

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '188351'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 13:45:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	26 Aug 2020 13:45:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:52

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:43:47

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:52

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:43:47

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:43:47

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Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:43:47



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Folder: Visit 1 Day 1

Form: Randomization

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[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:43:47

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Folder: Visit 1 Day 1

Form: Randomization

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[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'No (N)'	(b) (4) Kristin Eis (b) (4)	01 Oct 2020 18:41:00
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 10:37:58
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:56:30

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Aug 2020 13:48:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 13:48:03
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	26 Aug 2020 13:48:03
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 13:45:56
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 13:45:56



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '26 Aug 2020' reason for change: New Information	(b) (4), (b) (6)	26 Aug 2020 13:48:03
User entered empty.		26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '09:45' reason for change: New Information	(b) (4), (b) (6)	26 Aug 2020 13:48:03
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '26 Aug 2020 09:45'	System	26 Aug 2020 13:48:03
User entered empty.	System	26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '98.3' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:48:03
User entered empty.		26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Other (Other)' reason for change: New Information	(b) (4), (b) (6)	26 Aug 2020 13:48:03
User entered empty.		26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:37:05
User entered 'Temporal' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	05 Sep 2020 20:01:42
User entered 'Infrared' reason for change: New Information	(b) (4), (b) (6)	26 Aug 2020 13:48:03
User entered empty.		26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '55' reason for change: New Information	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:48:03
User entered empty.		26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'bpm'	System	26 Aug 2020 13:48:03
User entered empty.	System	26 Aug 2020 13:45:56



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '16' reason for change: New Information	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:48:03
User entered empty.		26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'breaths/min'	System	26 Aug 2020 13:48:03
User entered empty.	System	26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '136' reason for change: New Information	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:48:03
User entered empty.		26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'mmHg'	System	26 Aug 2020 13:48:03
User entered empty.	System	26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 06:46:49
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Sharon Mathys (b) (4) (b) (4)	17 Sep 2020 15:56:47
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:17:47
User entered '52' reason for change: New Information	(b) (4), (b) (6)	26 Aug 2020 13:48:03
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'mmHg'	System	26 Aug 2020 13:48:03
User entered empty.	System	26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:45:56



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User accepted default value 'Post-Dose (POSTDOSE)'		26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Aug 2020 15:11:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 15:11:55
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	26 Aug 2020 15:11:55
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 13:45:56
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '26 Aug 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:11:55
User entered empty.		26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:37:05
User entered '11:10' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	05 Sep 2020 19:59:39
User entered '11:05' reason for change: New Information	(b) (4), (b) (6)	26 Aug 2020 15:11:55
User entered empty.		26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '26 Aug 2020 11:10'	System	05 Sep 2020 19:59:39
User entered '26 Aug 2020 11:05'	System	26 Aug 2020 15:11:55
User entered empty.	System	26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '97.5' F reason for change: New Information	(b) (4), (b) (6)	26 Aug 2020 15:11:55
User entered empty.		26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Other (Other)' reason for change: New Information	(b) (4), (b) (6)	26 Aug 2020 15:11:55
User entered empty.		26 Aug 2020 13:45:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:37:05
User entered 'Temporal' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	05 Sep 2020 20:01:42
User entered 'Infrared' reason for change: New Information	(b) (4), (b) (6)	26 Aug 2020 15:11:55
User entered empty.		26 Aug 2020 13:45:56



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '49' reason for change: New Information	(b) (4)	26 Aug 2020 15:11:55
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'bpm'	System	26 Aug 2020 15:11:55
User entered empty.	System	26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '15' reason for change: New Information	(b) (4) (b) (4), (b) (6)	26 Aug 2020 15:11:55
User entered empty.		26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'breaths/min'	System	26 Aug 2020 15:11:55
User entered empty.	System	26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 14:30:06
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs participant was not distressed and has htn' (Site from System).	Sharon Mathys (b) (4) (b) (4)	05 Sep 2020 19:57:32
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Aug 2020 15:11:55
User entered '160' reason for change: New Information	(b) (4), (b) (6)	26 Aug 2020 15:11:55
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'mmHg'	System	26 Aug 2020 15:11:55
User entered empty.	System	26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Sep 2020 06:46:55
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Sharon Mathys (b) (4) (b) (4)	17 Sep 2020 15:56:56
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:17:47
User entered '52' reason for change: New Information	(b) (4), (b) (6)	26 Aug 2020 15:11:55
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 13:45:56

US3522274

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'mmHg'	System	26 Aug 2020 15:11:55
User entered empty.	System	26 Aug 2020 13:45:56



US3522274

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:48:45

US3522274

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:48:45

US3522274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:41:25

US3522274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:41:25

US3522274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:41:25

US3522274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 14:41:25

US3522274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:41:25

US3522274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '10:40'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:41:25



US3522274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '26 Aug 2020 10:40'	System	26 Aug 2020 14:41:25

US3522274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:41:25

US3522274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'ONCE'	System	26 Aug 2020 14:41:25

US3522274

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 14:41:25

US3522274

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:51:14

US3522274

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:51:14

US3522274

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '09:51'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:51:14

US3522274

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '26 Aug 2020 09:51'	System	26 Aug 2020 13:51:14



US3522274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:58:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:59:58

US3522274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	26 Aug 2020 13:59:58

US3522274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:59:58

US3522274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '09:58'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:59:58

US3522274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '26 Aug 2020 09:58'	System	26 Aug 2020 13:59:58

US3522274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	26 Aug 2020 13:59:58

US3522274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:59:58

US3522274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:59:58



US3522274

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered empty.	System	26 Aug 2020 13:59:58

US3522274

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:46:06

US3522274

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '1'	System	26 Aug 2020 13:46:06

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:12:04', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '0354b79b-a112-489d-95f2-6abd38ae6589' User entered 'Yes (Y)'	System	26 Aug 2020 15:12:39
	System	26 Aug 2020 15:12:39

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:12:14', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '0354b79b-a112-489d-95f2-6abd38ae6589' User entered '97.1'	System	26 Aug 2020 15:12:39
	System	26 Aug 2020 15:12:39

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:12:21', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '0354b79b-a112-489d-95f2-6abd38ae6589' User entered 'No (N)'	System	26 Aug 2020 15:12:39
	System	26 Aug 2020 15:12:39

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:12:28', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '0354b79b-a112-489d-95f2-6abd38ae6589' User entered '26 Aug 2020 11:12'	System	26 Aug 2020 15:12:39
	System	26 Aug 2020 15:12:39



US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Aug 2020 11:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Aug 2020 13:30'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:12:34', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b0c37e9f-ca4d-4432-81d2-d818d3820efd' User entered 'Yes (Y)'	System	26 Aug 2020 20:13:01
	System	26 Aug 2020 20:13:01

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:12:46', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b0c37e9f-ca4d-4432-81d2-d818d3820efd' User entered '97.4'	System	26 Aug 2020 20:13:01
	System	26 Aug 2020 20:13:01

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:12:52', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b0c37e9f-ca4d-4432-81d2-d818d3820efd' User entered 'No (N)'	System	26 Aug 2020 20:13:01
	System	26 Aug 2020 20:13:01

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:12:57', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b0c37e9f-ca4d-4432-81d2-d818d3820efd' User entered '26 Aug 2020 16:12'	System	26 Aug 2020 20:13:01
	System	26 Aug 2020 20:13:01

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Aug 2020 14:25'	System	26 Aug 2020 14:41:25



US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 2'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:47:51', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '034b9cd4-613a-47f7-9972-bd9b10ec5c92' User entered 'Yes (Y)'	System	27 Aug 2020 23:48:16
	System	27 Aug 2020 23:48:16

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:48:02', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '034b9cd4-613a-47f7-9972-bd9b10ec5c92' User entered '98.6'	System	27 Aug 2020 23:48:16
	System	27 Aug 2020 23:48:16

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:48:07', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '034b9cd4-613a-47f7-9972-bd9b10ec5c92'	System	27 Aug 2020 23:48:16
User entered 'No (N)'	System	27 Aug 2020 23:48:16

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:48:12', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '034b9cd4-613a-47f7-9972-bd9b10ec5c92'	System	27 Aug 2020 23:48:16
User entered '27 Aug 2020 19:48'	System	27 Aug 2020 23:48:16

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 14:41:25



US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 3'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:01:54', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'f93506e4-842c-481a-b34b-1cbea90ca11e' User entered 'Yes (Y)'	System	28 Aug 2020 16:03:17
	System	28 Aug 2020 16:03:17

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:02:01', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'f93506e4-842c-481a-b34b-1cbea90ca11e' User entered '97.5'	System	28 Aug 2020 16:03:17
	System	28 Aug 2020 16:03:17

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:02:06', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'f93506e4-842c-481a-b34b-1cbea90ca11e' User entered 'No (N)'	System	28 Aug 2020 16:03:17
	System	28 Aug 2020 16:03:17

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:02:12', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'f93506e4-842c-481a-b34b-1cbea90ca11e' User entered '28 Aug 2020 12:02'	System	28 Aug 2020 16:03:17
	System	28 Aug 2020 16:03:17

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 4'	System	26 Aug 2020 14:41:25



US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:03:53', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ca8fed80-ddd4-4918-8418-afe57c11806e' User entered 'Yes (Y)'	System	29 Aug 2020 19:04:11
	System	29 Aug 2020 19:04:11

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:02', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ca8fed80-ddd4-4918-8418-afe57c11806e' User entered '98.8'	System	29 Aug 2020 19:04:11
	System	29 Aug 2020 19:04:11

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:05', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ca8fed80-ddd4-4918-8418-afe57c11806e' User entered 'No (N)'	System	29 Aug 2020 19:04:11
	System	29 Aug 2020 19:04:11

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:09', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ca8fed80-ddd4-4918-8418-afe57c11806e' User entered '29 Aug 2020 15:04'	System	29 Aug 2020 19:04:11
	System	29 Aug 2020 19:04:11

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 5'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:20:16', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fcfeaffe-fa0c-4a4c-8540-10dacfb33c89'	System	30 Aug 2020 18:20:37
User entered 'Yes (Y)'	System	30 Aug 2020 18:20:37



US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:20:25', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fcfeaffe-fa0c-4a4c-8540-10dacfb33c89'	System	30 Aug 2020 18:20:37
User entered '98.1'	System	30 Aug 2020 18:20:37

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:20:28', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fcfeaffe-fa0c-4a4c-8540-10dacfb33c89'	System	30 Aug 2020 18:20:37
User entered 'No (N)'	System	30 Aug 2020 18:20:37

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:20:33', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fcfeaffe-fa0c-4a4c-8540-10dacfb33c89' User entered '30 Aug 2020 14:20'	System	30 Aug 2020 18:20:37
	System	30 Aug 2020 18:20:37

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 6'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:29:30', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '840947c0-2d46-40f7-9df8-8c8d681f7e95'	System	01 Sep 2020 00:29:47
User entered 'Yes (Y)'	System	01 Sep 2020 00:29:47

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:29:36', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '840947c0-2d46-40f7-9df8-8c8d681f7e95' User entered '98.1'	System	01 Sep 2020 00:29:47
	System	01 Sep 2020 00:29:47



US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:29:40', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '840947c0-2d46-40f7-9df8-8c8d681f7e95'	System	01 Sep 2020 00:29:47
User entered 'No (N)'	System	01 Sep 2020 00:29:47

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:29:44', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '840947c0-2d46-40f7-9df8-8c8d681f7e95'	System	01 Sep 2020 00:29:47
User entered '31 Aug 2020 20:29'	System	01 Sep 2020 00:29:47

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 7'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:25:45', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '67afde6e-bd98-4d5a-a0d3-615456b56a1c' User entered 'Yes (Y)'	System	01 Sep 2020 23:26:02
	System	01 Sep 2020 23:26:02

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:25:52', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '67afde6e-bd98-4d5a-a0d3-615456b56a1c' User entered '99.1'	System	01 Sep 2020 23:26:02
	System	01 Sep 2020 23:26:02

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:25:55', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '67afde6e-bd98-4d5a-a0d3-615456b56a1c' User entered 'No (N)'	System	01 Sep 2020 23:26:02
	System	01 Sep 2020 23:26:02



US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:25:58', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '67afde6e-bd98-4d5a-a0d3-615456b56a1c' User entered '01 Sep 2020 19:25'	System	01 Sep 2020 23:26:02
	System	01 Sep 2020 23:26:02

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:00:21', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '05037d3a-a430-4d36-86dd-29b1f8077aac'	System	26 Aug 2020 15:00:44
User entered 'None (1)'	System	26 Aug 2020 15:00:44

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:00:25', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '05037d3a-a430-4d36-86dd-29b1f8077aac' User entered 'No (N)'	System	26 Aug 2020 15:00:44
	System	26 Aug 2020 15:00:44

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:00:29', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '05037d3a-a430-4d36-86dd-29b1f8077aac' User entered 'No (N)'	System	26 Aug 2020 15:00:44
	System	26 Aug 2020 15:00:44

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:00:33', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '05037d3a-a430-4d36-86dd-29b1f8077aac' User entered 'None (1)'	System	26 Aug 2020 15:00:44
	System	26 Aug 2020 15:00:44



US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:00:42', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '05037d3a-a430-4d36-86dd-29b1f8077aac' User entered '26 Aug 2020 11:00'	System	26 Aug 2020 15:00:44
	System	26 Aug 2020 15:00:44

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Aug 2020 11:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Aug 2020 13:30'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:13:53', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '17242c78-f09e-4285-86a6-31d5c3e03494' User entered 'None (1)'	System	26 Aug 2020 20:14:17
	System	26 Aug 2020 20:14:17

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:13:57', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '17242c78-f09e-4285-86a6-31d5c3e03494' User entered 'No (N)'	System	26 Aug 2020 20:14:17
	System	26 Aug 2020 20:14:17

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:14:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '17242c78-f09e-4285-86a6-31d5c3e03494' User entered 'No (N)'	System	26 Aug 2020 20:14:17
	System	26 Aug 2020 20:14:17

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:14:06', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '17242c78-f09e-4285-86a6-31d5c3e03494'	System	26 Aug 2020 20:14:17
User entered 'None (1)'	System	26 Aug 2020 20:14:17



US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:14:13', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '17242c78-f09e-4285-86a6-31d5c3e03494' User entered '26 Aug 2020 16:14'	System	26 Aug 2020 20:14:17
	System	26 Aug 2020 20:14:17

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Aug 2020 14:25'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 2'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:48:28', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '81f47c69-423f-4fdc-8070-11c08e1371ae' User entered 'None (1)'	System	27 Aug 2020 23:49:03
	System	27 Aug 2020 23:49:03

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:48:36', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '81f47c69-423f-4fdc-8070-11c08e1371ae' User entered 'No (N)'	System	27 Aug 2020 23:49:03
	System	27 Aug 2020 23:49:03

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:48:48', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '81f47c69-423f-4fdc-8070-11c08e1371ae' User entered 'No (N)'	System	27 Aug 2020 23:49:03
	System	27 Aug 2020 23:49:03

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:48:52', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '81f47c69-423f-4fdc-8070-11c08e1371ae'	System	27 Aug 2020 23:49:03
User entered 'None (1)'	System	27 Aug 2020 23:49:03



US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:48:58', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '81f47c69-423f-4fdc-8070-11c08e1371ae' User entered '27 Aug 2020 19:48'	System	27 Aug 2020 23:49:03
	System	27 Aug 2020 23:49:03

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 3'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:01:25', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '0807bcd8-35c3-498b-9c08-16d030fcc12d' User entered 'None (1)'	System	28 Aug 2020 16:02:27
	System	28 Aug 2020 16:02:27

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:01:30', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '0807bcd8-35c3-498b-9c08-16d030fcc12d' User entered 'No (N)'	System	28 Aug 2020 16:02:27
	System	28 Aug 2020 16:02:27

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:01:34', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '0807bcd8-35c3-498b-9c08-16d030fcc12d' User entered 'No (N)'	System	28 Aug 2020 16:02:27
	System	28 Aug 2020 16:02:27

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:01:37', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '0807bcd8-35c3-498b-9c08-16d030fcc12d' User entered 'None (1)'	System	28 Aug 2020 16:02:27
	System	28 Aug 2020 16:02:27



US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:01:42', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '0807bcd8-35c3-498b-9c08-16d030fcc12d' User entered '28 Aug 2020 12:01'	System	28 Aug 2020 16:02:27
	System	28 Aug 2020 16:02:27

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 4'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:13', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4cb04c7a-1334-4d2e-9a83-9c1ae824f564' User entered 'None (1)'	System	29 Aug 2020 19:04:27
	System	29 Aug 2020 19:04:27

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:16', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4cb04c7a-1334-4d2e-9a83-9c1ae824f564'	System	29 Aug 2020 19:04:27
User entered 'No (N)'	System	29 Aug 2020 19:04:27

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:18', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4cb04c7a-1334-4d2e-9a83-9c1ae824f564'	System	29 Aug 2020 19:04:27
User entered 'No (N)'	System	29 Aug 2020 19:04:27

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:20', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4cb04c7a-1334-4d2e-9a83-9c1ae824f564' User entered 'None (1)'	System	29 Aug 2020 19:04:27
	System	29 Aug 2020 19:04:27



US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:23', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4cb04c7a-1334-4d2e-9a83-9c1ae824f564' User entered '29 Aug 2020 15:04'	System	29 Aug 2020 19:04:27
	System	29 Aug 2020 19:04:27

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 5'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:19:15', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fe70c456-5142-4169-adcc-9ca662e697fd' User entered 'None (1)'	System	30 Aug 2020 18:19:31
	System	30 Aug 2020 18:19:31

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:19:18', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fe70c456-5142-4169-adcc-9ca662e697fd'	System	30 Aug 2020 18:19:31
User entered 'No (N)'	System	30 Aug 2020 18:19:31

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:19:21', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fe70c456-5142-4169-adcc-9ca662e697fd'	System	30 Aug 2020 18:19:31
User entered 'No (N)'	System	30 Aug 2020 18:19:31

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:19:24', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fe70c456-5142-4169-adcc-9ca662e697fd'	System	30 Aug 2020 18:19:31
User entered 'None (1)'	System	30 Aug 2020 18:19:31



US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:19:27', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fe70c456-5142-4169-adcc-9ca662e697fd' User entered '30 Aug 2020 14:19'	System	30 Aug 2020 18:19:31
	System	30 Aug 2020 18:19:31

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 6'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:29:48', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1b4c8598-da3b-4f67-86be-25b4bdd955b8'	System	01 Sep 2020 00:29:59
User entered 'None (1)'	System	01 Sep 2020 00:29:59

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:29:50', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1b4c8598-da3b-4f67-86be-25b4bdd955b8'	System	01 Sep 2020 00:29:59
User entered 'No (N)'	System	01 Sep 2020 00:29:59

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:29:52', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1b4c8598-da3b-4f67-86be-25b4bdd955b8'	System	01 Sep 2020 00:29:59
User entered 'No (N)'	System	01 Sep 2020 00:29:59

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:29:54', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1b4c8598-da3b-4f67-86be-25b4bdd955b8'	System	01 Sep 2020 00:29:59
User entered 'None (1)'	System	01 Sep 2020 00:29:59



US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:29:57', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1b4c8598-da3b-4f67-86be-25b4bdd955b8' User entered '31 Aug 2020 20:29'	System	01 Sep 2020 00:29:59
	System	01 Sep 2020 00:29:59

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 7'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:26:02', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4447bcd4-cf0d-4050-898b-ccebc1b192bd' User entered 'None (1)'	System	01 Sep 2020 23:26:13
	System	01 Sep 2020 23:26:13

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:26:04', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4447bcd4-cf0d-4050-898b-ccebc1b192bd' User entered 'No (N)'	System	01 Sep 2020 23:26:13
	System	01 Sep 2020 23:26:13

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:26:06', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4447bcd4-cf0d-4050-898b-ccebc1b192bd'	System	01 Sep 2020 23:26:13
User entered 'No (N)'	System	01 Sep 2020 23:26:13

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:26:08', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4447bcd4-cf0d-4050-898b-ccebc1b192bd' User entered 'None (1)'	System	01 Sep 2020 23:26:13
	System	01 Sep 2020 23:26:13



US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:26:10', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4447bcd4-cf0d-4050-898b-ccebc1b192bd' User entered '01 Sep 2020 19:26'	System	01 Sep 2020 23:26:13
	System	01 Sep 2020 23:26:13

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:12:40', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '81eac750-6d3f-4e47-8977-42e5aaa6dc87' User entered 'None (0)'	System	26 Aug 2020 15:13:12
	System	26 Aug 2020 15:13:12

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:12:46', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '81eac750-6d3f-4e47-8977-42e5aaa6dc87' User entered 'None (0)'	System	26 Aug 2020 15:13:12
	System	26 Aug 2020 15:13:12

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:12:48', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '81eac750-6d3f-4e47-8977-42e5aaa6dc87' User entered 'None (0)'	System	26 Aug 2020 15:13:12
	System	26 Aug 2020 15:13:12

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:12:51', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '81eac750-6d3f-4e47-8977-42e5aaa6dc87' User entered 'None (0)'	System	26 Aug 2020 15:13:12
	System	26 Aug 2020 15:13:12



US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:12:54', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '81eac750-6d3f-4e47-8977-42e5aaa6dc87' User entered 'None (0)'	System	26 Aug 2020 15:13:12
	System	26 Aug 2020 15:13:12

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:12:57', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '81eac750-6d3f-4e47-8977-42e5aaa6dc87' User entered 'None (0)'	System	26 Aug 2020 15:13:12
	System	26 Aug 2020 15:13:12

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:13:01', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '81eac750-6d3f-4e47-8977-42e5aaa6dc87' User entered 'Yes (Y)'	System	26 Aug 2020 15:13:12
	System	26 Aug 2020 15:13:12

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T11:13:07', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '81eac750-6d3f-4e47-8977-42e5aaa6dc87' User entered '26 Aug 2020 11:13'	System	26 Aug 2020 15:13:12
	System	26 Aug 2020 15:13:12

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Aug 2020 11:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Aug 2020 13:30'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:13:06', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '631a57a9-4d81-48f0-8469-81cdcc042b62'	System	26 Aug 2020 20:13:50
User entered 'None (0)'	System	26 Aug 2020 20:13:50



US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:13:12', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '631a57a9-4d81-48f0-8469-81cdcc042b62' User entered 'None (0)'	System	26 Aug 2020 20:13:50
	System	26 Aug 2020 20:13:50

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:13:18', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '631a57a9-4d81-48f0-8469-81cdcc042b62' User entered 'None (0)'	System	26 Aug 2020 20:13:50
	System	26 Aug 2020 20:13:50

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:13:30', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '631a57a9-4d81-48f0-8469-81cdcc042b62' User entered 'None (0)'	System	26 Aug 2020 20:13:50
	System	26 Aug 2020 20:13:50

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:13:32', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '631a57a9-4d81-48f0-8469-81cdcc042b62' User entered 'None (0)'	System	26 Aug 2020 20:13:50
	System	26 Aug 2020 20:13:50

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:13:35', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '631a57a9-4d81-48f0-8469-81cdcc042b62'	System	26 Aug 2020 20:13:50
User entered 'None (0)'	System	26 Aug 2020 20:13:50

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:13:43', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '631a57a9-4d81-48f0-8469-81cdcc042b62'	System	26 Aug 2020 20:13:50
User entered 'No (N)'	System	26 Aug 2020 20:13:50

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-26T16:13:47', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '631a57a9-4d81-48f0-8469-81cdcc042b62' User entered '26 Aug 2020 16:13'	System	26 Aug 2020 20:13:50
	System	26 Aug 2020 20:13:50

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Aug 2020 14:25'	System	26 Aug 2020 14:41:25



US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 2'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:49:05', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '00327963-7327-4f76-b354-25eab018e822'	System	27 Aug 2020 23:49:34
User entered 'None (0)'	System	27 Aug 2020 23:49:34

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:49:13', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '00327963-7327-4f76-b354-25eab018e822'	System	27 Aug 2020 23:49:34
User entered 'Some interference with activity (2)'	System	27 Aug 2020 23:49:34

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:49:18', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '00327963-7327-4f76-b354-25eab018e822'	System	27 Aug 2020 23:49:34
User entered 'None (0)'	System	27 Aug 2020 23:49:34

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:49:21', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '00327963-7327-4f76-b354-25eab018e822'	System	27 Aug 2020 23:49:34
User entered 'None (0)'	System	27 Aug 2020 23:49:34

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:49:24', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '00327963-7327-4f76-b354-25eab018e822'	System	27 Aug 2020 23:49:34
User entered 'None (0)'	System	27 Aug 2020 23:49:34

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:49:27', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '00327963-7327-4f76-b354-25eab018e822'	System	27 Aug 2020 23:49:34
User entered 'None (0)'	System	27 Aug 2020 23:49:34



US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:49:30', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '00327963-7327-4f76-b354-25eab018e822'	System	27 Aug 2020 23:49:34
User entered 'No (N)'	System	27 Aug 2020 23:49:34

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-27T19:49:32', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '00327963-7327-4f76-b354-25eab018e822'	System	27 Aug 2020 23:49:34
User entered '27 Aug 2020 19:49'	System	27 Aug 2020 23:49:34

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 3'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:02:18', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1a8b5da4-7a5d-4a9b-b728-50dc13017909' User entered 'None (0)'	System	28 Aug 2020 16:04:01
	System	28 Aug 2020 16:04:01

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:02:20', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1a8b5da4-7a5d-4a9b-b728-50dc13017909' User entered 'None (0)'	System	28 Aug 2020 16:04:01
	System	28 Aug 2020 16:04:01

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:02:23', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1a8b5da4-7a5d-4a9b-b728-50dc13017909'	System	28 Aug 2020 16:04:01
User entered 'None (0)'	System	28 Aug 2020 16:04:01



US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:02:26', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1a8b5da4-7a5d-4a9b-b728-50dc13017909' User entered 'None (0)'	System	28 Aug 2020 16:04:01
	System	28 Aug 2020 16:04:01

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:02:29', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1a8b5da4-7a5d-4a9b-b728-50dc13017909' User entered 'None (0)'	System	28 Aug 2020 16:04:01
	System	28 Aug 2020 16:04:01

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:02:32', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1a8b5da4-7a5d-4a9b-b728-50dc13017909' User entered 'None (0)'	System	28 Aug 2020 16:04:01
	System	28 Aug 2020 16:04:01

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:02:36', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1a8b5da4-7a5d-4a9b-b728-50dc13017909' User entered 'No (N)'	System	28 Aug 2020 16:04:01
	System	28 Aug 2020 16:04:01

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-28T12:02:49', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1a8b5da4-7a5d-4a9b-b728-50dc13017909' User entered '28 Aug 2020 12:02'	System	28 Aug 2020 16:04:01
	System	28 Aug 2020 16:04:01

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 4'	System	26 Aug 2020 14:41:25



US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:27', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '9166adec-1ca5-4b09-9445-c8fd7c7400ee' User entered 'None (0)'	System	29 Aug 2020 19:04:42
	System	29 Aug 2020 19:04:42

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:29', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '9166adec-1ca5-4b09-9445-c8fd7c7400ee' User entered 'None (0)'	System	29 Aug 2020 19:04:42
	System	29 Aug 2020 19:04:42

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:30', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '9166adec-1ca5-4b09-9445-c8fd7c7400ee' User entered 'None (0)'	System	29 Aug 2020 19:04:42
	System	29 Aug 2020 19:04:42

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:31', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '9166adec-1ca5-4b09-9445-c8fd7c7400ee' User entered 'None (0)'	System	29 Aug 2020 19:04:42
	System	29 Aug 2020 19:04:42

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:33', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '9166adec-1ca5-4b09-9445-c8fd7c7400ee' User entered 'None (0)'	System	29 Aug 2020 19:04:42
	System	29 Aug 2020 19:04:42

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:35', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '9166adec-1ca5-4b09-9445-c8fd7c7400ee' User entered 'None (0)'	System	29 Aug 2020 19:04:42
	System	29 Aug 2020 19:04:42

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:37', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '9166adec-1ca5-4b09-9445-c8fd7c7400ee' User entered 'No (N)'	System	29 Aug 2020 19:04:42
	System	29 Aug 2020 19:04:42

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-29T15:04:40', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '9166adec-1ca5-4b09-9445-c8fd7c7400ee' User entered '29 Aug 2020 15:04'	System	29 Aug 2020 19:04:42
	System	29 Aug 2020 19:04:42



US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 5'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:19:32', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b40a13e5-768f-44d4-8a43-5ca949a9a14e' User entered 'None (0)'	System	30 Aug 2020 18:20:10
	System	30 Aug 2020 18:20:10

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:19:41', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b40a13e5-768f-44d4-8a43-5ca949a9a14e' User entered 'Some interference with activity (2)'	System	30 Aug 2020 18:20:10
	System	30 Aug 2020 18:20:10

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:19:53', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b40a13e5-768f-44d4-8a43-5ca949a9a14e' User entered 'Some interference with activity (2)'	System	30 Aug 2020 18:20:10
	System	30 Aug 2020 18:20:10

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:19:58', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b40a13e5-768f-44d4-8a43-5ca949a9a14e' User entered 'Some interference with activity (2)'	System	30 Aug 2020 18:20:10
	System	30 Aug 2020 18:20:10

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:20:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b40a13e5-768f-44d4-8a43-5ca949a9a14e' User entered 'None (0)'	System	30 Aug 2020 18:20:10
	System	30 Aug 2020 18:20:10



US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:20:02', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b40a13e5-768f-44d4-8a43-5ca949a9a14e' User entered 'None (0)'	System	30 Aug 2020 18:20:10
	System	30 Aug 2020 18:20:10

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:20:05', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b40a13e5-768f-44d4-8a43-5ca949a9a14e' User entered 'No (N)'	System	30 Aug 2020 18:20:10
	System	30 Aug 2020 18:20:10

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-30T14:20:08', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b40a13e5-768f-44d4-8a43-5ca949a9a14e' User entered '30 Aug 2020 14:20'	System	30 Aug 2020 18:20:10
	System	30 Aug 2020 18:20:10

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 6'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:30:01', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fb33489f-f4ce-44e3-99df-feaf39713dff'	System	01 Sep 2020 00:30:27
User entered 'None (0)'	System	01 Sep 2020 00:30:27

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:30:07', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fb33489f-f4ce-44e3-99df-feaf39713dff'	System	01 Sep 2020 00:30:27
User entered 'None (0)'	System	01 Sep 2020 00:30:27



US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:30:11', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fb33489f-f4ce-44e3-99df-feaf39713dff'	System	01 Sep 2020 00:30:27
User entered 'None (0)'	System	01 Sep 2020 00:30:27

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:30:13', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fb33489f-f4ce-44e3-99df-feaf39713dff' User entered 'None (0)'	System	01 Sep 2020 00:30:27
	System	01 Sep 2020 00:30:27

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:30:16', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fb33489f-f4ce-44e3-99df-feaf39713dff'	System	01 Sep 2020 00:30:27
User entered 'None (0)'	System	01 Sep 2020 00:30:27

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:30:18', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fb33489f-f4ce-44e3-99df-feaf39713dff'	System	01 Sep 2020 00:30:27
User entered 'None (0)'	System	01 Sep 2020 00:30:27

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:30:20', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fb33489f-f4ce-44e3-99df-feaf39713dff'	System	01 Sep 2020 00:30:27
User entered 'No (N)'	System	01 Sep 2020 00:30:27

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-08-31T20:30:23', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'fb33489f-f4ce-44e3-99df-feaf39713dff'	System	01 Sep 2020 00:30:27
User entered '31 Aug 2020 20:30'	System	01 Sep 2020 00:30:27

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 14:41:25



US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 7'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:26:14', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7133c16d-e88e-4d08-9c58-bbec3ca2475a' User entered 'None (0)'	System	01 Sep 2020 23:26:30
	System	01 Sep 2020 23:26:30

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:26:15', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7133c16d-e88e-4d08-9c58-bbec3ca2475a' User entered 'None (0)'	System	01 Sep 2020 23:26:30
	System	01 Sep 2020 23:26:30

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:26:16', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7133c16d-e88e-4d08-9c58-bbec3ca2475a' User entered 'None (0)'	System	01 Sep 2020 23:26:30
	System	01 Sep 2020 23:26:30

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:26:18', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7133c16d-e88e-4d08-9c58-bbec3ca2475a' User entered 'None (0)'	System	01 Sep 2020 23:26:30
	System	01 Sep 2020 23:26:30

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:26:19', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7133c16d-e88e-4d08-9c58-bbec3ca2475a' User entered 'None (0)'	System	01 Sep 2020 23:26:30
	System	01 Sep 2020 23:26:30

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:26:21', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7133c16d-e88e-4d08-9c58-bbec3ca2475a' User entered 'None (0)'	System	01 Sep 2020 23:26:30
	System	01 Sep 2020 23:26:30

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:26:24', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7133c16d-e88e-4d08-9c58-bbec3ca2475a' User entered 'No (N)'	System	01 Sep 2020 23:26:30
	System	01 Sep 2020 23:26:30



US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-01T19:26:28', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7133c16d-e88e-4d08-9c58-bbec3ca2475a' User entered '01 Sep 2020 19:26'	System	01 Sep 2020 23:26:30
	System	01 Sep 2020 23:26:30

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 14:41:25

US3522274

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	02 Sep 2020 13:23:59

US3522274

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '2 Sep 2020'	(b) (4) Alandra White (b) (4)	02 Sep 2020 13:23:59

US3522274

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alandra White (b) (4)	02 Sep 2020 13:23:59

US3522274

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'EDIARY REVIEWED. MILD FATIGUE REPORTED ON DAYS 2 & 5 WITH MILD MUSCLE/JOINT ACHES ALSO OCCURRING ON DAY 5. SYMPTOMS DID NOT INTERFERE WITH DAILY ACTIVITIES AND RESOLVED WITHOUT INTERVENTION/MEDICATION' reason for change: Data Entry Error	Alandra White (b) (4)	02 Sep 2020 13:24:19
User entered 'eDiary reviewed. Mild fatigue reported on Days 2 & 5 with mild muscle/joint aches also occurring on Day 5. Symptoms did not interfere with daily activities and resolved without intervention/medication. Patient states that he is feeling well and has no current concerns.' (non-conformant).	Alandra White (b) (4)	02 Sep 2020 13:23:59

US3522274

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) Alandra White (b) (4)	09 Sep 2020 12:52:20



US3522274

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '1'	System	09 Sep 2020 12:52:20

US3522274

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	09 Sep 2020 12:55:36

US3522274

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '9 Sep 2020'	(b) (4) Alandra White (b) (4)	09 Sep 2020 12:55:36

US3522274

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alandra White (b) (4)	09 Sep 2020 12:55:36

US3522274

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	Alandra White (b) (4)	09 Sep 2020 12:55:36

US3522274

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	Alandra White (b) (4) (b) (4)	09 Sep 2020 12:55:40

US3522274

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '1'	System	09 Sep 2020 12:55:40

US3522274

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:48:19



US3522274

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '16 Sep 2020'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:48:19

US3522274

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:48:19

US3522274

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:48:19

US3522274

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Sep 2020 13:48:24

US3522274

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '1'	System	16 Sep 2020 13:48:24

US3522274

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:02:41

US3522274

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:02:41

US3522274

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:02:41



US3522274

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'VISIT2'	System	23 Sep 2020 16:02:41

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '12:00'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '23 Sep 2020 12:00'	System	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:52



US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '63'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'bpm'	System	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '16'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'breaths/min'	System	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '137'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'mmHg'	System	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '67'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:03:52



US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'mmHg'	System	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User closed query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	(b) (4) System	23 Sep 2020 16:49:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 16:49:24
User opened query 'Response to were vital signs assessed is No, but data is provided below. Please correct.' (Site from System).	System	23 Sep 2020 16:49:13
User entered 'No (N)'	(b) (4), (b) (6)	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '23 Sep 2020' reason for change: Data Entry Error	(b) (4)	23 Sep 2020 16:49:13
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '12:50' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:49:13
User entered empty.		23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '23 Sep 2020 12:50'	System	23 Sep 2020 16:49:13
User entered empty.	System	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '98.1' F reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:49:13
User entered empty.		23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Sep 2020 16:49:13
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:03:52



US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'temporal' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:49:13
User entered empty.		23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '62' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:49:13
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'bpm'	System	23 Sep 2020 16:49:13
User entered empty.	System	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '21' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:49:13
User entered empty.		23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'breaths/min'	System	23 Sep 2020 16:49:13
User entered empty.	System	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '122' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:49:13
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'mmHg'	System	23 Sep 2020 16:49:13
User entered empty.	System	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 09:18:46
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	(b) (4), (b) (6)	23 Sep 2020 16:53:09
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		23 Sep 2020 16:49:13
User entered '56' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Sep 2020 16:49:13
User entered empty.	(b) (4), (b) (6)	23 Sep 2020 16:03:52



US3522274

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'mmHg'	System	23 Sep 2020 16:49:13
User entered empty.	System	23 Sep 2020 16:03:52

US3522274

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:02:55

US3522274

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:02:55

US3522274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:30:54

US3522274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:30:54

US3522274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:30:54

US3522274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 16:30:54

US3522274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:30:54



US3522274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '12:20'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:30:54

US3522274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '23 Sep 2020 12:20'	System	23 Sep 2020 16:30:54

US3522274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:30:54

US3522274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'ONCE'	System	23 Sep 2020 16:30:54

US3522274

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 16:30:54

US3522274

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:15:32

US3522274

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:15:32

US3522274

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '12:10'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:15:32



US3522274

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '23 Sep 2020 12:10'	System	23 Sep 2020 16:15:32

US3522274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:58:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:16:03

US3522274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	23 Sep 2020 16:16:03

US3522274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:16:03

US3522274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '12:15'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:16:03

US3522274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:58:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '23 Sep 2020 12:15'	System	23 Sep 2020 16:16:03

US3522274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:52

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	23 Sep 2020 16:16:03

US3522274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:16:03



US3522274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:16:03

US3522274

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:58:52

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered empty.	System	23 Sep 2020 16:16:03

US3522274

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Sep 2020 16:17:37

US3522274

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '1'	System	23 Sep 2020 16:17:37

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T12:47:29', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1e33979c-aec6-421b-a344-9e271f611598'	System	23 Sep 2020 16:47:48
User entered 'Yes (Y)'	System	23 Sep 2020 16:47:48

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T12:47:34', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1e33979c-aec6-421b-a344-9e271f611598' User entered '98.1'	System	23 Sep 2020 16:47:48
	System	23 Sep 2020 16:47:48

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T12:47:40', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1e33979c-aec6-421b-a344-9e271f611598'	System	23 Sep 2020 16:47:48
User entered 'No (N)'	System	23 Sep 2020 16:47:48



US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T12:47:45', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '1e33979c-aec6-421b-a344-9e271f611598' User entered '23 Sep 2020 12:47'	System	23 Sep 2020 16:47:48
	System	23 Sep 2020 16:47:48

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '23 Sep 2020 12:40'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '23 Sep 2020 15:10'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:53:10', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '3713dcfe-0990-4543-aece-f2a920074799'	System	24 Sep 2020 00:53:29
User entered 'Yes (Y)'	System	24 Sep 2020 00:53:29

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:53:18', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '3713dcfe-0990-4543-aece-f2a920074799' User entered '98.2'	System	24 Sep 2020 00:53:29
	System	24 Sep 2020 00:53:29

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:53:21', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '3713dcfe-0990-4543-aece-f2a920074799'	System	24 Sep 2020 00:53:29
User entered 'No (N)'	System	24 Sep 2020 00:53:29

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:53:24', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '3713dcfe-0990-4543-aece-f2a920074799'	System	24 Sep 2020 00:53:29
User entered '23 Sep 2020 20:53'	System	24 Sep 2020 00:53:29



US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '23 Sep 2020 16:05'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 2'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:18:29', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '8bbb555e-fa6a-43fd-84b8-22c26187b615' User entered 'Yes (Y)'	System	25 Sep 2020 01:18:45
	System	25 Sep 2020 01:18:45

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:18:35', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '8bbb555e-fa6a-43fd-84b8-22c26187b615' User entered '98.1'	System	25 Sep 2020 01:18:45
	System	25 Sep 2020 01:18:45

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:18:38', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '8bbb555e-fa6a-43fd-84b8-22c26187b615'	System	25 Sep 2020 01:18:45
User entered 'No (N)'	System	25 Sep 2020 01:18:45

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:18:41', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '8bbb555e-fa6a-43fd-84b8-22c26187b615' User entered '24 Sep 2020 21:18'	System	25 Sep 2020 01:18:45
	System	25 Sep 2020 01:18:45

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 16:30:54



US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 3'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:15:18', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '06f762d1-4f54-4f37-8cbd-cec2f44df5a6' User entered 'Yes (Y)'	System	26 Sep 2020 02:15:34
	System	26 Sep 2020 02:15:34

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:15:25', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '06f762d1-4f54-4f37-8cbd-cec2f44df5a6' User entered '98.1'	System	26 Sep 2020 02:15:34
	System	26 Sep 2020 02:15:34

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:15:29', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '06f762d1-4f54-4f37-8cbd-cec2f44df5a6'	System	26 Sep 2020 02:15:34
User entered 'No (N)'	System	26 Sep 2020 02:15:34

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:15:32', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '06f762d1-4f54-4f37-8cbd-cec2f44df5a6'	System	26 Sep 2020 02:15:34
User entered '25 Sep 2020 22:15'	System	26 Sep 2020 02:15:34

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 16:30:54



US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 4'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:12:42', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '60bbfa49-b579-4eb2-9887-24ac8b9dd145' User entered 'Yes (Y)'	System	27 Sep 2020 00:12:58
	System	27 Sep 2020 00:12:58

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:12:49', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '60bbfa49-b579-4eb2-9887-24ac8b9dd145' User entered '98.4'	System	27 Sep 2020 00:12:58
	System	27 Sep 2020 00:12:58

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:12:51', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '60bbfa49-b579-4eb2-9887-24ac8b9dd145'	System	27 Sep 2020 00:12:58
User entered 'No (N)'	System	27 Sep 2020 00:12:58

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:12:55', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '60bbfa49-b579-4eb2-9887-24ac8b9dd145' User entered '26 Sep 2020 20:12'	System	27 Sep 2020 00:12:58
	System	27 Sep 2020 00:12:58

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 5'	System	23 Sep 2020 16:30:54



US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:29:31', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4fbc5738-995a-4f2c-acea-dd3bc7462e9d'	System	28 Sep 2020 03:29:47
User entered 'Yes (Y)'	System	28 Sep 2020 03:29:47

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:29:38', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4fbc5738-995a-4f2c-acea-dd3bc7462e9d'	System	28 Sep 2020 03:29:47
User entered '98.2'	System	28 Sep 2020 03:29:47

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:29:42', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4fbc5738-995a-4f2c-acea-dd3bc7462e9d'	System	28 Sep 2020 03:29:47
User entered 'No (N)'	System	28 Sep 2020 03:29:47

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:29:45', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4fbc5738-995a-4f2c-acea-dd3bc7462e9d' User entered '27 Sep 2020 23:29'	System	28 Sep 2020 03:29:47
	System	28 Sep 2020 03:29:47

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 6'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:56:34', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7c5446b7-652b-49d7-8091-e6c09ce7e0c0' User entered 'Yes (Y)'	System	29 Sep 2020 11:56:54
	System	29 Sep 2020 11:56:54



US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:56:40', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7c5446b7-652b-49d7-8091-e6c09ce7e0c0' User entered '97.7'	System	29 Sep 2020 11:56:54
	System	29 Sep 2020 11:56:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:56:46', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7c5446b7-652b-49d7-8091-e6c09ce7e0c0' User entered 'No (N)'	System	29 Sep 2020 11:56:54
	System	29 Sep 2020 11:56:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:56:49', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7c5446b7-652b-49d7-8091-e6c09ce7e0c0' User entered '29 Sep 2020 07:56'	System	29 Sep 2020 11:56:54
	System	29 Sep 2020 11:56:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 7'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:16:19', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b7d69b1c-8394-43f9-bc3f-a07f125ce7c5'	System	30 Sep 2020 02:16:34
User entered 'Yes (Y)'	System	30 Sep 2020 02:16:34

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:16:26', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b7d69b1c-8394-43f9-bc3f-a07f125ce7c5' User entered '97.9'	System	30 Sep 2020 02:16:34
	System	30 Sep 2020 02:16:34



US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:16:28', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b7d69b1c-8394-43f9-bc3f-a07f125ce7c5'	System	30 Sep 2020 02:16:34
User entered 'No (N)'	System	30 Sep 2020 02:16:34

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:16:31', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b7d69b1c-8394-43f9-bc3f-a07f125ce7c5' User entered '29 Sep 2020 22:16'	System	30 Sep 2020 02:16:34
	System	30 Sep 2020 02:16:34

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T14:55:18', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '21d9002b-bc96-467e-aaa9-bf69957bd7de'	System	23 Sep 2020 18:55:46
User entered 'None (1)'	System	23 Sep 2020 18:55:46

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T14:55:24', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '21d9002b-bc96-467e-aaa9-bf69957bd7de' User entered 'No (N)'	System	23 Sep 2020 18:55:46
	System	23 Sep 2020 18:55:46

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T14:55:32', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '21d9002b-bc96-467e-aaa9-bf69957bd7de'	System	23 Sep 2020 18:55:46
User entered 'No (N)'	System	23 Sep 2020 18:55:46



US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T14:55:40', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '21d9002b-bc96-467e-aaa9-bf69957bd7de'	System	23 Sep 2020 18:55:46
User entered 'None (1)'	System	23 Sep 2020 18:55:46

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T14:55:43', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '21d9002b-bc96-467e-aaa9-bf69957bd7de' User entered '23 Sep 2020 14:55'	System	23 Sep 2020 18:55:46
	System	23 Sep 2020 18:55:46

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '23 Sep 2020 12:40'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '23 Sep 2020 15:10'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:53:35', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '75db5dc5-f8ec-496a-870a-b9606531bfac'	System	24 Sep 2020 00:54:06
User entered 'None (1)'	System	24 Sep 2020 00:54:06

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:53:46', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '75db5dc5-f8ec-496a-870a-b9606531bfac' User entered 'No (N)'	System	24 Sep 2020 00:54:06
	System	24 Sep 2020 00:54:06

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:53:54', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '75db5dc5-f8ec-496a-870a-b9606531bfac' User entered 'No (N)'	System	24 Sep 2020 00:54:06
	System	24 Sep 2020 00:54:06



US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:53:57', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '75db5dc5-f8ec-496a-870a-b9606531bfac'	System	24 Sep 2020 00:54:06
User entered 'None (1)'	System	24 Sep 2020 00:54:06

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:54:02', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '75db5dc5-f8ec-496a-870a-b9606531bfac'	System	24 Sep 2020 00:54:06
User entered '23 Sep 2020 20:54'	System	24 Sep 2020 00:54:06

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '23 Sep 2020 16:05'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 2'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:18:46', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '5f44c902-5a3f-442b-98a1-4d6bb6017bb4' User entered 'None (1)'	System	25 Sep 2020 01:19:07
	System	25 Sep 2020 01:19:07

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:18:49', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '5f44c902-5a3f-442b-98a1-4d6bb6017bb4'	System	25 Sep 2020 01:19:07
User entered 'No (N)'	System	25 Sep 2020 01:19:07

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:18:59', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '5f44c902-5a3f-442b-98a1-4d6bb6017bb4'	System	25 Sep 2020 01:19:07
User entered 'No (N)'	System	25 Sep 2020 01:19:07



US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:19:01', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '5f44c902-5a3f-442b-98a1-4d6bb6017bb4' User entered 'None (1)'	System	25 Sep 2020 01:19:07
	System	25 Sep 2020 01:19:07

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:19:05', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '5f44c902-5a3f-442b-98a1-4d6bb6017bb4'	System	25 Sep 2020 01:19:07
User entered '24 Sep 2020 21:19'	System	25 Sep 2020 01:19:07

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 3'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:15:36', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '79dcb319-9928-403c-9be3-ccf563e45b7a' User entered 'None (1)'	System	26 Sep 2020 02:15:55
	System	26 Sep 2020 02:15:55

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:15:39', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '79dcb319-9928-403c-9be3-ccf563e45b7a' User entered 'No (N)'	System	26 Sep 2020 02:15:55
	System	26 Sep 2020 02:15:55

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:15:47', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '79dcb319-9928-403c-9be3-ccf563e45b7a' User entered 'No (N)'	System	26 Sep 2020 02:15:55
	System	26 Sep 2020 02:15:55



US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:15:50', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '79dcb319-9928-403c-9be3-ccf563e45b7a'	System	26 Sep 2020 02:15:55
User entered 'None (1)'	System	26 Sep 2020 02:15:55

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:15:53', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '79dcb319-9928-403c-9be3-ccf563e45b7a' User entered '25 Sep 2020 22:15'	System	26 Sep 2020 02:15:55
	System	26 Sep 2020 02:15:55

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 4'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:13:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7740c34c-ffe6-4369-b1b1-f490e77c1f12'	System	27 Sep 2020 00:13:12
User entered 'None (1)'	System	27 Sep 2020 00:13:12

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:13:03', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7740c34c-ffe6-4369-b1b1-f490e77c1f12'	System	27 Sep 2020 00:13:12
User entered 'No (N)'	System	27 Sep 2020 00:13:12

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:13:05', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7740c34c-ffe6-4369-b1b1-f490e77c1f12'	System	27 Sep 2020 00:13:12
User entered 'No (N)'	System	27 Sep 2020 00:13:12



US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:13:07', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7740c34c-ffe6-4369-b1b1-f490e77c1f12'	System	27 Sep 2020 00:13:12
User entered 'None (1)'	System	27 Sep 2020 00:13:12

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:13:10', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7740c34c-ffe6-4369-b1b1-f490e77c1f12'	System	27 Sep 2020 00:13:12
User entered '26 Sep 2020 20:13'	System	27 Sep 2020 00:13:12

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 5'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:29:49', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c0966fe0-4002-4d6c-a4fb-970ab0e29800'	System	28 Sep 2020 03:30:05
User entered 'None (1)'	System	28 Sep 2020 03:30:05

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:29:52', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c0966fe0-4002-4d6c-a4fb-970ab0e29800' User entered 'No (N)'	System	28 Sep 2020 03:30:05
	System	28 Sep 2020 03:30:05

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:29:54', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c0966fe0-4002-4d6c-a4fb-970ab0e29800' User entered 'No (N)'	System	28 Sep 2020 03:30:05
	System	28 Sep 2020 03:30:05



US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:29:56', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c0966fe0-4002-4d6c-a4fb-970ab0e29800'	System	28 Sep 2020 03:30:05
User entered 'None (1)'	System	28 Sep 2020 03:30:05

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:29:59', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c0966fe0-4002-4d6c-a4fb-970ab0e29800' User entered '27 Sep 2020 23:29'	System	28 Sep 2020 03:30:05
	System	28 Sep 2020 03:30:05

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 6'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:56:54', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '16882960-f25e-41ed-bd98-85d5e1d45c92'	System	29 Sep 2020 11:57:11
User entered 'None (1)'	System	29 Sep 2020 11:57:11

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:56:57', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '16882960-f25e-41ed-bd98-85d5e1d45c92'	System	29 Sep 2020 11:57:11
User entered 'No (N)'	System	29 Sep 2020 11:57:11

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:56:59', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '16882960-f25e-41ed-bd98-85d5e1d45c92'	System	29 Sep 2020 11:57:11
User entered 'No (N)'	System	29 Sep 2020 11:57:11



US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:57:04', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '16882960-f25e-41ed-bd98-85d5e1d45c92'	System	29 Sep 2020 11:57:11
User entered 'None (1)'	System	29 Sep 2020 11:57:11

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:57:07', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '16882960-f25e-41ed-bd98-85d5e1d45c92'	System	29 Sep 2020 11:57:11
User entered '29 Sep 2020 07:57'	System	29 Sep 2020 11:57:11

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 7'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:16:35', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '717fd1eb-57ee-456a-821d-0ee8045ef8eb' User entered 'None (1)'	System	30 Sep 2020 02:16:47
	System	30 Sep 2020 02:16:47

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:16:38', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '717fd1eb-57ee-456a-821d-0ee8045ef8eb' User entered 'No (N)'	System	30 Sep 2020 02:16:47
	System	30 Sep 2020 02:16:47

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:16:40', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '717fd1eb-57ee-456a-821d-0ee8045ef8eb' User entered 'No (N)'	System	30 Sep 2020 02:16:47
	System	30 Sep 2020 02:16:47



US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:16:42', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '717fd1eb-57ee-456a-821d-0ee8045ef8eb'	System	30 Sep 2020 02:16:47
User entered 'None (1)'	System	30 Sep 2020 02:16:47

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:16:45', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '717fd1eb-57ee-456a-821d-0ee8045ef8eb' User entered '29 Sep 2020 22:16'	System	30 Sep 2020 02:16:47
	System	30 Sep 2020 02:16:47

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T14:55:55', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ef36d69b-bd99-429c-a2c7-590762340482'	System	23 Sep 2020 18:56:31
User entered 'None (0)'	System	23 Sep 2020 18:56:31

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T14:55:57', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ef36d69b-bd99-429c-a2c7-590762340482'	System	23 Sep 2020 18:56:31
User entered 'None (0)'	System	23 Sep 2020 18:56:31

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T14:56:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ef36d69b-bd99-429c-a2c7-590762340482'	System	23 Sep 2020 18:56:31
User entered 'None (0)'	System	23 Sep 2020 18:56:31



US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T14:56:02', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ef36d69b-bd99-429c-a2c7-590762340482' User entered 'None (0)'	System	23 Sep 2020 18:56:31
	System	23 Sep 2020 18:56:31

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T14:56:05', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ef36d69b-bd99-429c-a2c7-590762340482'	System	23 Sep 2020 18:56:31
User entered 'None (0)'	System	23 Sep 2020 18:56:31

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T14:56:07', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ef36d69b-bd99-429c-a2c7-590762340482'	System	23 Sep 2020 18:56:31
User entered 'None (0)'	System	23 Sep 2020 18:56:31

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T14:56:10', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ef36d69b-bd99-429c-a2c7-590762340482'	System	23 Sep 2020 18:56:31
User entered 'No (N)'	System	23 Sep 2020 18:56:31

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T14:56:27', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ef36d69b-bd99-429c-a2c7-590762340482'	System	23 Sep 2020 18:56:31
User entered '23 Sep 2020 14:56'	System	23 Sep 2020 18:56:31

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '23 Sep 2020 12:40'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '23 Sep 2020 15:10'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 16:30:54



US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:54:08', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c8cf59b2-d96a-4f03-afff-510df602cc88'	System	24 Sep 2020 00:54:25
User entered 'None (0)'	System	24 Sep 2020 00:54:25

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:54:10', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c8cf59b2-d96a-4f03-afff-510df602cc88'	System	24 Sep 2020 00:54:25
User entered 'None (0)'	System	24 Sep 2020 00:54:25

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:54:11', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c8cf59b2-d96a-4f03-afff-510df602cc88'	System	24 Sep 2020 00:54:25
User entered 'None (0)'	System	24 Sep 2020 00:54:25

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:54:13', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c8cf59b2-d96a-4f03-afff-510df602cc88' User entered 'None (0)'	System	24 Sep 2020 00:54:25
	System	24 Sep 2020 00:54:25

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:54:15', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c8cf59b2-d96a-4f03-afff-510df602cc88'	System	24 Sep 2020 00:54:25
User entered 'None (0)'	System	24 Sep 2020 00:54:25

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:54:18', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c8cf59b2-d96a-4f03-afff-510df602cc88'	System	24 Sep 2020 00:54:25
User entered 'None (0)'	System	24 Sep 2020 00:54:25

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:54:20', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c8cf59b2-d96a-4f03-afff-510df602cc88'	System	24 Sep 2020 00:54:25
User entered 'No (N)'	System	24 Sep 2020 00:54:25

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-23T20:54:23', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c8cf59b2-d96a-4f03-afff-510df602cc88'	System	24 Sep 2020 00:54:25
User entered '23 Sep 2020 20:54'	System	24 Sep 2020 00:54:25



US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '23 Sep 2020 16:05'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 2'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:19:08', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6108892b-eea1-4e75-8668-2f416e253d8e' User entered 'None (0)'	System	25 Sep 2020 01:19:24
	System	25 Sep 2020 01:19:24

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:19:09', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6108892b-eea1-4e75-8668-2f416e253d8e' User entered 'None (0)'	System	25 Sep 2020 01:19:24
	System	25 Sep 2020 01:19:24

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:19:11', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6108892b-eea1-4e75-8668-2f416e253d8e' User entered 'None (0)'	System	25 Sep 2020 01:19:24
	System	25 Sep 2020 01:19:24

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:19:12', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6108892b-eea1-4e75-8668-2f416e253d8e' User entered 'None (0)'	System	25 Sep 2020 01:19:24
	System	25 Sep 2020 01:19:24

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:19:14', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6108892b-eea1-4e75-8668-2f416e253d8e' User entered 'None (0)'	System	25 Sep 2020 01:19:24
	System	25 Sep 2020 01:19:24



US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:19:16', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6108892b-eea1-4e75-8668-2f416e253d8e' User entered 'None (0)'	System	25 Sep 2020 01:19:24
	System	25 Sep 2020 01:19:24

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:19:19', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6108892b-eea1-4e75-8668-2f416e253d8e' User entered 'No (N)'	System	25 Sep 2020 01:19:24
	System	25 Sep 2020 01:19:24

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-24T21:19:21', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6108892b-eea1-4e75-8668-2f416e253d8e' User entered '24 Sep 2020 21:19'	System	25 Sep 2020 01:19:24
	System	25 Sep 2020 01:19:24

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 3'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:15:57', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7e4ad6d3-8d23-4fb2-8a32-7437da7f4a9f' User entered 'None (0)'	System	26 Sep 2020 02:16:13
	System	26 Sep 2020 02:16:13

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:15:58', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7e4ad6d3-8d23-4fb2-8a32-7437da7f4a9f' User entered 'None (0)'	System	26 Sep 2020 02:16:13
	System	26 Sep 2020 02:16:13



US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:16:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7e4ad6d3-8d23-4fb2-8a32-7437da7f4a9f' User entered 'None (0)'	System	26 Sep 2020 02:16:13
	System	26 Sep 2020 02:16:13

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:16:02', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7e4ad6d3-8d23-4fb2-8a32-7437da7f4a9f' User entered 'None (0)'	System	26 Sep 2020 02:16:13
	System	26 Sep 2020 02:16:13

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:16:04', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7e4ad6d3-8d23-4fb2-8a32-7437da7f4a9f' User entered 'None (0)'	System	26 Sep 2020 02:16:13
	System	26 Sep 2020 02:16:13

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:16:05', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7e4ad6d3-8d23-4fb2-8a32-7437da7f4a9f' User entered 'None (0)'	System	26 Sep 2020 02:16:13
	System	26 Sep 2020 02:16:13

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:16:08', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7e4ad6d3-8d23-4fb2-8a32-7437da7f4a9f' User entered 'No (N)'	System	26 Sep 2020 02:16:13
	System	26 Sep 2020 02:16:13

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-25T22:16:11', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '7e4ad6d3-8d23-4fb2-8a32-7437da7f4a9f' User entered '25 Sep 2020 22:16'	System	26 Sep 2020 02:16:13
	System	26 Sep 2020 02:16:13

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 16:30:54



US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 4'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:13:19', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'be16b5ff-30a0-48c3-8d1c-7930a67a2773' User entered 'None (0)'	System	27 Sep 2020 00:13:36
	System	27 Sep 2020 00:13:36

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:13:20', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'be16b5ff-30a0-48c3-8d1c-7930a67a2773' User entered 'None (0)'	System	27 Sep 2020 00:13:36
	System	27 Sep 2020 00:13:36

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:13:21', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'be16b5ff-30a0-48c3-8d1c-7930a67a2773' User entered 'None (0)'	System	27 Sep 2020 00:13:36
	System	27 Sep 2020 00:13:36

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:13:23', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'be16b5ff-30a0-48c3-8d1c-7930a67a2773' User entered 'None (0)'	System	27 Sep 2020 00:13:36
	System	27 Sep 2020 00:13:36

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:13:25', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'be16b5ff-30a0-48c3-8d1c-7930a67a2773' User entered 'None (0)'	System	27 Sep 2020 00:13:36
	System	27 Sep 2020 00:13:36

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:13:28', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'be16b5ff-30a0-48c3-8d1c-7930a67a2773' User entered 'None (0)'	System	27 Sep 2020 00:13:36
	System	27 Sep 2020 00:13:36

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:13:31', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'be16b5ff-30a0-48c3-8d1c-7930a67a2773'	System	27 Sep 2020 00:13:36
User entered 'No (N)'	System	27 Sep 2020 00:13:36



US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-26T20:13:34', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'be16b5ff-30a0-48c3-8d1c-7930a67a2773'	System	27 Sep 2020 00:13:36
User entered '26 Sep 2020 20:13'	System	27 Sep 2020 00:13:36

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 5'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:30:03', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6f36fb12-7c48-4e98-b12e-cbd9e412aaff' User entered 'None (0)'	System	28 Sep 2020 03:30:20
	System	28 Sep 2020 03:30:20

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:30:04', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6f36fb12-7c48-4e98-b12e-cbd9e412aaff'	System	28 Sep 2020 03:30:20
User entered 'None (0)'	System	28 Sep 2020 03:30:20

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:30:06', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6f36fb12-7c48-4e98-b12e-cbd9e412aaff'	System	28 Sep 2020 03:30:20
User entered 'None (0)'	System	28 Sep 2020 03:30:20

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:30:07', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6f36fb12-7c48-4e98-b12e-cbd9e412aaff'	System	28 Sep 2020 03:30:20
User entered 'None (0)'	System	28 Sep 2020 03:30:20



US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:30:09', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6f36fb12-7c48-4e98-b12e-cbd9e412aaff'	System	28 Sep 2020 03:30:20
User entered 'None (0)'	System	28 Sep 2020 03:30:20

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:30:11', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6f36fb12-7c48-4e98-b12e-cbd9e412aaff' User entered 'None (0)'	System	28 Sep 2020 03:30:20
	System	28 Sep 2020 03:30:20

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:30:13', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6f36fb12-7c48-4e98-b12e-cbd9e412aaff' User entered 'No (N)'	System	28 Sep 2020 03:30:20
	System	28 Sep 2020 03:30:20

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-27T23:30:16', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '6f36fb12-7c48-4e98-b12e-cbd9e412aaff' User entered '27 Sep 2020 23:30'	System	28 Sep 2020 03:30:20
	System	28 Sep 2020 03:30:20

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 6'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:57:14', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4d5a4d44-3cac-4eb6-85dc-5fad7f1dc31f' User entered 'None (0)'	System	29 Sep 2020 11:57:36
	System	29 Sep 2020 11:57:36



US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:57:16', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4d5a4d44-3cac-4eb6-85dc-5fad7f1dc31f' User entered 'None (0)'	System	29 Sep 2020 11:57:36
	System	29 Sep 2020 11:57:36

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:57:19', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4d5a4d44-3cac-4eb6-85dc-5fad7f1dc31f' User entered 'None (0)'	System	29 Sep 2020 11:57:36
	System	29 Sep 2020 11:57:36

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:57:21', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4d5a4d44-3cac-4eb6-85dc-5fad7f1dc31f' User entered 'None (0)'	System	29 Sep 2020 11:57:36
	System	29 Sep 2020 11:57:36

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:57:24', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4d5a4d44-3cac-4eb6-85dc-5fad7f1dc31f' User entered 'None (0)'	System	29 Sep 2020 11:57:36
	System	29 Sep 2020 11:57:36

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:57:26', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4d5a4d44-3cac-4eb6-85dc-5fad7f1dc31f' User entered 'None (0)'	System	29 Sep 2020 11:57:36
	System	29 Sep 2020 11:57:36

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:57:30', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4d5a4d44-3cac-4eb6-85dc-5fad7f1dc31f'	System	29 Sep 2020 11:57:36
User entered 'No (N)'	System	29 Sep 2020 11:57:36

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T07:57:33', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '4d5a4d44-3cac-4eb6-85dc-5fad7f1dc31f' User entered '29 Sep 2020 07:57'	System	29 Sep 2020 11:57:36
	System	29 Sep 2020 11:57:36

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 16:30:54



US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	23 Sep 2020 16:30:54
User entered 'Day 7'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:16:49', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a14a3c01-954c-40a3-9006-ea6de0a39e19'	System	30 Sep 2020 02:17:15
User entered 'None (0)'	System	30 Sep 2020 02:17:15

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:16:51', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a14a3c01-954c-40a3-9006-ea6de0a39e19'	System	30 Sep 2020 02:17:15
User entered 'None (0)'	System	30 Sep 2020 02:17:15

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:16:54', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a14a3c01-954c-40a3-9006-ea6de0a39e19'	System	30 Sep 2020 02:17:15
User entered 'None (0)'	System	30 Sep 2020 02:17:15

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:16:57', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a14a3c01-954c-40a3-9006-ea6de0a39e19' User entered 'None (0)'	System	30 Sep 2020 02:17:15
	System	30 Sep 2020 02:17:15

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:17:01', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a14a3c01-954c-40a3-9006-ea6de0a39e19'	System	30 Sep 2020 02:17:15
User entered 'None (0)'	System	30 Sep 2020 02:17:15

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:17:06', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a14a3c01-954c-40a3-9006-ea6de0a39e19'	System	30 Sep 2020 02:17:15
User entered 'None (0)'	System	30 Sep 2020 02:17:15



US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:17:10', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a14a3c01-954c-40a3-9006-ea6de0a39e19' User entered 'No (N)'	System	30 Sep 2020 02:17:15
	System	30 Sep 2020 02:17:15

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-09-29T22:17:13', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a14a3c01-954c-40a3-9006-ea6de0a39e19' User entered '29 Sep 2020 22:17'	System	30 Sep 2020 02:17:15
	System	30 Sep 2020 02:17:15

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 16:30:54

US3522274

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 07:58:52

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 16:30:54

US3522274

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:17:51

US3522274

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '2 Oct 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:34:51
User entered '01 Oct 2020' reason for change: Data Entry Error	Kristin Eis (b) (4)	01 Oct 2020 18:44:00
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:17:51

US3522274

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4), (b) (6)	02 Oct 2020 17:34:51
User entered 'Contact Not Made (CONTACT NOT MADE)'		30 Sep 2020 16:17:51

US3522274

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Clicard not activated. Says wrong birthday. No ongoing AEs, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure.' reason for change: New Information	(b) (4) (b) (4), (b) (6)	02 Oct 2020 17:34:51
User entered 'Voicemail left'	(b) (4), (b) (6)	30 Sep 2020 16:17:51



US3522274

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 16:17:38

US3522274

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '1'	System	30 Sep 2020 16:17:38

US3522274

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:55:43

US3522274

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:55:43

US3522274

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:55:43

US3522274

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered "'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk.'"	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:55:43

US3522274

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 13:55:46

US3522274

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '1'	System	07 Oct 2020 13:55:46



US3522274

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:29:18

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US3522274

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:37:05
User entered '15 Oct 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	15 Oct 2020 17:54:28
User entered '14 Oct 2020'	(b) (4), (b) (6)	14 Oct 2020 13:29:18

US3522274

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:37:05
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	15 Oct 2020 17:54:28
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	14 Oct 2020 13:29:18

US3522274

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:37:05
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, or Covid-19 exposure risk' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	15 Oct 2020 17:54:28
User entered 'Voicemail left'	(b) (4), (b) (6)	14 Oct 2020 13:29:18

US3522274

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:29:07

US3522274

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '1'	System	14 Oct 2020 13:29:07

US3522274

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:22:59
	(b) (4)	

US3522274

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '28 Oct 2020'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:22:59
	(b) (4)	



US3522274

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Clinic (Clinic)'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:22:59
	(b) (4)	

US3522274

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'VISIT3'	System	28 Oct 2020 16:22:59

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:24:02
	(b) (4)	

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '28 Oct 2020'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:24:02
	(b) (4)	

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '12:00'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:24:02
	(b) (4)	

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '28 Oct 2020 12:00'	System	28 Oct 2020 16:24:02

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '98.2' F	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:24:02
	(b) (4)	

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Other (Other)'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:24:02
	(b) (4)	



US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'temporal'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:24:02
	(b) (4)	

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	16 Feb 2021 18:37:05
User entered '67'	Alayna Wilder (b) (4) (b) (4)	28 Oct 2020 16:24:02

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'bpm'	System	28 Oct 2020 16:24:02

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '18'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:24:02
	(b) (4)	

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'breaths/min'	System	28 Oct 2020 16:24:02

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '125'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:24:02
	(b) (4)	

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'mmHg'	System	28 Oct 2020 16:24:02

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Oct 2020 06:55:35
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Sharon Mathys (b) (4) (b) (4)	28 Oct 2020 17:20:45
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		28 Oct 2020 16:24:02
User entered '57'	Alayna Wilder (b) (4) (b) (4)	28 Oct 2020 16:24:02



US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'mmHg'	System	28 Oct 2020 16:24:02

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31

US3522274

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31

US3522274

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:24:11
	(b) (4)	

US3522274

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '28 Oct 2020'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:24:11
	(b) (4)	

US3522274

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:24:25
	(b) (4)	

US3522274

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '28 Oct 2020'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:24:25
	(b) (4)	

US3522274

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered '12:15'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:24:25
	(b) (4)	



US3522274

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '28 Oct 2020 12:15'	System	28 Oct 2020 16:24:25

US3522274

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	16 Feb 2021 18:37:05
User entered 'Yes (Y)'	(b) (4) Alayna Wilder (b) (4)	28 Oct 2020 16:24:34
	(b) (4)	

US3522274

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered '1'	System	28 Oct 2020 16:24:34

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 64'	System	26 Aug 2020 14:41:25

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-10-26T07:55:08', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a162452c-2889-4b9c-8fe7-61dda2521329'	System	26 Oct 2020 11:55:25
User entered 'No (N)'	System	26 Oct 2020 11:55:25

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-10-26T07:55:14', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a162452c-2889-4b9c-8fe7-61dda2521329'	System	26 Oct 2020 11:55:25
User entered 'No (N)'	System	26 Oct 2020 11:55:25

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-10-26T07:55:21', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a162452c-2889-4b9c-8fe7-61dda2521329' User entered '26 Oct 2020 07:55:21'	System	26 Oct 2020 11:55:25
	System	26 Oct 2020 11:55:25

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered '26 Oct 2020 00:01'	System	26 Aug 2020 14:41:25



US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered '30 Oct 2020 23:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 71'	System	26 Aug 2020 14:41:25

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-11-04T12:00:44', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '5f2f2c8d-251f-41c5-b660-f101829cf68e'	System	04 Nov 2020 17:02:49
User entered 'No (N)'	System	04 Nov 2020 17:02:49

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-11-04T12:00:52', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '5f2f2c8d-251f-41c5-b660-f101829cf68e'	System	04 Nov 2020 17:02:49
User entered 'No (N)'	System	04 Nov 2020 17:02:49

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-11-04T12:00:56', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '5f2f2c8d-251f-41c5-b660-f101829cf68e' User entered '04 Nov 2020 12:00:56'	System	04 Nov 2020 17:02:49
	System	04 Nov 2020 17:02:49

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered '02 Nov 2020 00:01'	System	26 Aug 2020 14:41:25

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered '06 Nov 2020 23:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered 'Day 78'	System	26 Aug 2020 14:41:25



US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-11-10T20:34:29', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'edb56d2c-6262-4ba2-9cfe-ff38faf94978'	System	11 Nov 2020 01:34:45
User entered 'No (N)'	System	11 Nov 2020 01:34:45

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-11-10T20:34:35', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'edb56d2c-6262-4ba2-9cfe-ff38faf94978'	System	11 Nov 2020 01:34:45
User entered 'No (N)'	System	11 Nov 2020 01:34:45

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0F588948-1CE4-494B-BD22-8069E653B529)', Time: '2020-11-10T20:34:39', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'edb56d2c-6262-4ba2-9cfe-ff38faf94978' User entered '10 Nov 2020 20:34:39'	System	11 Nov 2020 01:34:45
	System	11 Nov 2020 01:34:45

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered '09 Nov 2020 00:01'	System	26 Aug 2020 14:41:25

US3522274

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 09:10:49
Data entry locked.	System	26 Aug 2020 14:41:25
User entered '13 Nov 2020 23:59'	System	26 Aug 2020 14:41:25

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-11-21T11:28:16', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'dbc5c84b-8834-4050-91a9-a68def467e2d'	System	21 Nov 2020 16:28:27
User entered 'No (N)'	System	21 Nov 2020 16:28:27

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-11-21T11:28:19', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'dbc5c84b-8834-4050-91a9-a68def467e2d'	System	21 Nov 2020 16:28:27
User entered 'No (N)'	System	21 Nov 2020 16:28:27



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-11-21T11:28:23', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'dbc5c84b-8834-4050-91a9-a68def467e2d' User entered '21 Nov 2020 11:28:23'	System	21 Nov 2020 16:28:27
	System	21 Nov 2020 16:28:27

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-11-29T07:50:38', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ec988aff-bcea-4d6a-b951-3dbfde56c8bf'	System	29 Nov 2020 12:50:51
User entered 'No (N)'	System	29 Nov 2020 12:50:51

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-11-29T07:50:45', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ec988aff-bcea-4d6a-b951-3dbfde56c8bf' User entered 'No (N)'	System	29 Nov 2020 12:50:51
	System	29 Nov 2020 12:50:51

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-11-29T07:50:48', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'ec988aff-bcea-4d6a-b951-3dbfde56c8bf' User entered '29 Nov 2020 07:50:48'	System	29 Nov 2020 12:50:51
	System	29 Nov 2020 12:50:51

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 00:28:11



**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-12-04T13:49:15', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '2805ef87-fe41-40c7-bf2f-da465e903164'	System	04 Dec 2020 18:49:30
User entered 'No (N)'	System	04 Dec 2020 18:49:30

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-12-04T13:49:18', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '2805ef87-fe41-40c7-bf2f-da465e903164'	System	04 Dec 2020 18:49:30
User entered 'No (N)'	System	04 Dec 2020 18:49:30

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-12-04T13:49:24', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '2805ef87-fe41-40c7-bf2f-da465e903164' User entered '04 Dec 2020 13:49:24'	System	04 Dec 2020 18:49:30
	System	04 Dec 2020 18:49:30

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:28:11



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-12-11T07:38:52', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '872db862-0212-47e2-8a83-7de8eb53fa0a'	System	11 Dec 2020 12:39:05
User entered 'No (N)'	System	11 Dec 2020 12:39:05

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-12-11T07:38:56', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '872db862-0212-47e2-8a83-7de8eb53fa0a'	System	11 Dec 2020 12:39:05
User entered 'No (N)'	System	11 Dec 2020 12:39:05

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-12-11T07:39:01', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '872db862-0212-47e2-8a83-7de8eb53fa0a' User entered '11 Dec 2020 07:39:01'	System	11 Dec 2020 12:39:05
	System	11 Dec 2020 12:39:05

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-12-18T08:02:30', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b8b2db1f-ee76-495f-af3c-1fd22569311d'	System	18 Dec 2020 13:02:41
User entered 'No (N)'	System	18 Dec 2020 13:02:41

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-12-18T08:02:32', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b8b2db1f-ee76-495f-af3c-1fd22569311d'	System	18 Dec 2020 13:02:41
User entered 'No (N)'	System	18 Dec 2020 13:02:41



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-12-18T08:02:37', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'b8b2db1f-ee76-495f-af3c-1fd22569311d' User entered '18 Dec 2020 08:02:37'	System	18 Dec 2020 13:02:41
	System	18 Dec 2020 13:02:41

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-12-25T08:43:45', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '289720c7-c0c7-4fb3-98a5-41d34382d20f' User entered 'No (N)'	System	25 Dec 2020 13:43:58
	System	25 Dec 2020 13:43:58

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-12-25T08:43:51', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '289720c7-c0c7-4fb3-98a5-41d34382d20f' User entered 'No (N)'	System	25 Dec 2020 13:43:58
	System	25 Dec 2020 13:43:58

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2020-12-25T08:43:55', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '289720c7-c0c7-4fb3-98a5-41d34382d20f' User entered '25 Dec 2020 08:43:55'	System	25 Dec 2020 13:43:58
	System	25 Dec 2020 13:43:58

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-01T08:41:27', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '573f386d-bb46-4cbc-9d02-2238650b73c8'	System	01 Jan 2021 13:41:39
User entered 'No (N)'	System	01 Jan 2021 13:41:39

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-01T08:41:30', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '573f386d-bb46-4cbc-9d02-2238650b73c8'	System	01 Jan 2021 13:41:39
User entered 'No (N)'	System	01 Jan 2021 13:41:39

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-01T08:41:34', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '573f386d-bb46-4cbc-9d02-2238650b73c8'	System	01 Jan 2021 13:41:39
User entered '01 Jan 2021 08:41:34'	System	01 Jan 2021 13:41:39

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-08T08:24:43', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a1c4dc5e-4146-42fd-aa1a-16a4141b3a51'	System	08 Jan 2021 13:24:58
User entered 'No (N)'	System	08 Jan 2021 13:24:58

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-08T08:24:51', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a1c4dc5e-4146-42fd-aa1a-16a4141b3a51'	System	08 Jan 2021 13:24:58
User entered 'No (N)'	System	08 Jan 2021 13:24:58

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-08T08:24:56', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a1c4dc5e-4146-42fd-aa1a-16a4141b3a51' User entered '08 Jan 2021 08:24:56'	System	08 Jan 2021 13:24:58
	System	08 Jan 2021 13:24:58

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-15T07:58:26', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '9480ac0f-1da6-44a2-8195-38eaa2df9e1a'	System	15 Jan 2021 12:58:41
User entered 'No (N)'	System	15 Jan 2021 12:58:41

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-15T07:58:30', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '9480ac0f-1da6-44a2-8195-38eaa2df9e1a'	System	15 Jan 2021 12:58:41
User entered 'No (N)'	System	15 Jan 2021 12:58:41



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-15T07:58:34', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '9480ac0f-1da6-44a2-8195-38eaa2df9e1a' User entered '15 Jan 2021 07:58:34'	System	15 Jan 2021 12:58:41
	System	15 Jan 2021 12:58:41

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-22T08:20:18', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c7693db4-9200-41db-9b61-7785cfe774da'	System	22 Jan 2021 13:20:28
User entered 'No (N)'	System	22 Jan 2021 13:20:28

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-22T08:20:22', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c7693db4-9200-41db-9b61-7785cfe774da' User entered 'No (N)'	System	22 Jan 2021 13:20:28
	System	22 Jan 2021 13:20:28

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-22T08:20:26', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c7693db4-9200-41db-9b61-7785cfe774da' User entered '22 Jan 2021 08:20:26'	System	22 Jan 2021 13:20:28
	System	22 Jan 2021 13:20:28

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 00:28:11



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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-29T08:23:51', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'faf141db-60e6-4cbd-8f1b-b1cdd99a3dcb'	System	29 Jan 2021 13:24:06
User entered 'No (N)'	System	29 Jan 2021 13:24:06

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-29T08:23:55', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'faf141db-60e6-4cbd-8f1b-b1cdd99a3dcb'	System	29 Jan 2021 13:24:06
User entered 'No (N)'	System	29 Jan 2021 13:24:06

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-01-29T08:24:02', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'faf141db-60e6-4cbd-8f1b-b1cdd99a3dcb' User entered '29 Jan 2021 08:24:02'	System	29 Jan 2021 13:24:06
	System	29 Jan 2021 13:24:06

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:28:11



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-02-05T09:09:20', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'eb7012c7-f4af-4405-9b95-a637088536d9' User entered 'No (N)'	System	05 Feb 2021 14:09:29
	System	05 Feb 2021 14:09:29

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-02-05T09:09:23', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'eb7012c7-f4af-4405-9b95-a637088536d9' User entered 'No (N)'	System	05 Feb 2021 14:09:29
	System	05 Feb 2021 14:09:29

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-02-05T09:09:26', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'eb7012c7-f4af-4405-9b95-a637088536d9'	System	05 Feb 2021 14:09:29
User entered '05 Feb 2021 09:09:26'	System	05 Feb 2021 14:09:29

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-02-14T12:24:55', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '307f5598-b9c9-4f44-8af6-685b3fc92675'	System	14 Feb 2021 17:25:06
User entered 'No (N)'	System	14 Feb 2021 17:25:06

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-02-14T12:25:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '307f5598-b9c9-4f44-8af6-685b3fc92675'	System	14 Feb 2021 17:25:06
User entered 'No (N)'	System	14 Feb 2021 17:25:06



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-02-14T12:25:02', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '307f5598-b9c9-4f44-8af6-685b3fc92675'	System	14 Feb 2021 17:25:06
User entered '14 Feb 2021 12:25:02'	System	14 Feb 2021 17:25:06

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 00:28:11



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-03-16T12:58:57-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'd8eb9361-50d1-4ad3-b588-6e34cf76b4cf'	System	16 Mar 2021 16:59:32
User entered 'Yes (Y)'	System	16 Mar 2021 16:59:32

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-03-16T12:59:00-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'd8eb9361-50d1-4ad3-b588-6e34cf76b4cf'	System	16 Mar 2021 16:59:32
User entered 'No (N)'	System	16 Mar 2021 16:59:32

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-03-16T12:59:03-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'd8eb9361-50d1-4ad3-b588-6e34cf76b4cf' User entered 'No (N)'	System	16 Mar 2021 16:59:32
	System	16 Mar 2021 16:59:32



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-03-16T12:59:08-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'd8eb9361-50d1-4ad3-b588-6e34cf76b4cf'	System	16 Mar 2021 16:59:32
User entered 'Yes (Y)'	System	16 Mar 2021 16:59:32

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Please 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-03-16T12:59:15-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'd8eb9361-50d1-4ad3-b588-6e34cf76b4cf'	System	16 Mar 2021 16:59:32
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Mar 2021 16:59:32

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-03-16T12:59:21-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'd8eb9361-50d1-4ad3-b588-6e34cf76b4cf' User entered '16 Mar 2021 12:59:21'	System	16 Mar 2021 16:59:32
	System	16 Mar 2021 16:59:32

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 00:28:11



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-03-30T11:21:04-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '06e1d707-8d6d-4a68-a812-797a270538dc'	System	30 Mar 2021 15:21:48
User entered 'Yes (Y)'	System	30 Mar 2021 15:21:48

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-03-30T11:21:10-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '06e1d707-8d6d-4a68-a812-797a270538dc' User entered 'No (N)'	System	30 Mar 2021 15:21:48
	System	30 Mar 2021 15:21:48

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-03-30T11:21:14-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '06e1d707-8d6d-4a68-a812-797a270538dc' User entered 'No (N)'	System	30 Mar 2021 15:21:48
	System	30 Mar 2021 15:21:48

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-03-30T11:21:21-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '06e1d707-8d6d-4a68-a812-797a270538dc'	System	30 Mar 2021 15:21:48
User entered 'Yes (Y)'	System	30 Mar 2021 15:21:48

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Please 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-03-30T11:21:28-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '06e1d707-8d6d-4a68-a812-797a270538dc'	System	30 Mar 2021 15:21:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	30 Mar 2021 15:21:48

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-03-30T11:21:32-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '06e1d707-8d6d-4a68-a812-797a270538dc' User entered '30 Mar 2021 11:21:32'	System	30 Mar 2021 15:21:48
	System	30 Mar 2021 15:21:48

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-02T08:28:20-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '99180ac7-e657-4fd0-9ffc-ea7ecad173a1'	System	02 Apr 2021 12:28:32
User entered 'No (N)'	System	02 Apr 2021 12:28:32

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-02T08:28:24-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '99180ac7-e657-4fd0-9ffc-ea7ecad173a1'	System	02 Apr 2021 12:28:32
User entered 'No (N)'	System	02 Apr 2021 12:28:32

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-02T08:28:28-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '99180ac7-e657-4fd0-9ffc-ea7ecad173a1'	System	02 Apr 2021 12:28:32
User entered '02 Apr 2021 08:28:28'	System	02 Apr 2021 12:28:32

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:28:11



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-09T08:39:19-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '48994b77-ac90-4d9c-a35c-06bb6861f481'	System	09 Apr 2021 12:39:30
User entered 'No (N)'	System	09 Apr 2021 12:39:30

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-09T08:39:23-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '48994b77-ac90-4d9c-a35c-06bb6861f481'	System	09 Apr 2021 12:39:30
User entered 'No (N)'	System	09 Apr 2021 12:39:30

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-09T08:39:27-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '48994b77-ac90-4d9c-a35c-06bb6861f481'	System	09 Apr 2021 12:39:30
User entered '09 Apr 2021 08:39:27'	System	09 Apr 2021 12:39:30

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-16T07:32:47-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '12f00551-9fe4-41fb-918f-2b68b1ee4742'	System	16 Apr 2021 11:33:00
User entered 'No (N)'	System	16 Apr 2021 11:33:00

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-16T07:32:50-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '12f00551-9fe4-41fb-918f-2b68b1ee4742'	System	16 Apr 2021 11:33:00
User entered 'No (N)'	System	16 Apr 2021 11:33:00



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-16T07:32:53-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '12f00551-9fe4-41fb-918f-2b68b1ee4742'	System	16 Apr 2021 11:33:00
User entered '16 Apr 2021 07:32:53'	System	16 Apr 2021 11:33:00

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-23T12:04:47-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '8f24e0ad-20fe-49fb-bcf6-e481c445104f'	System	23 Apr 2021 16:10:07
User entered 'No (N)'	System	23 Apr 2021 16:10:07

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-23T12:04:50-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '8f24e0ad-20fe-49fb-bcf6-e481c445104f'	System	23 Apr 2021 16:10:07
User entered 'No (N)'	System	23 Apr 2021 16:10:07

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-23T12:04:53-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: '8f24e0ad-20fe-49fb-bcf6-e481c445104f' User entered '23 Apr 2021 12:04:53'	System	23 Apr 2021 16:10:07
	System	23 Apr 2021 16:10:07

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-30T09:19:13-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a45017e6-f4f6-4223-ab1c-2d173c0d22d3'	System	30 Apr 2021 13:19:24
User entered 'No (N)'	System	30 Apr 2021 13:19:24

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

Have you been exposed to someone with 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 (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-30T09:19:15-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a45017e6-f4f6-4223-ab1c-2d173c0d22d3'	System	30 Apr 2021 13:19:24
User entered 'No (N)'	System	30 Apr 2021 13:19:24

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-04-30T09:19:18-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'a45017e6-f4f6-4223-ab1c-2d173c0d22d3'	System	30 Apr 2021 13:19:24
User entered '30 Apr 2021 09:19:18'	System	30 Apr 2021 13:19:24

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:28:11



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:28:11



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 00:28:11



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 00:28:11



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 00:28:11



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

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**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 00:28:11

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

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 00:28:11

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 00:28:11

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 00:28:11

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 00:28:11

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 00:28:11

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:28:11

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:28:11

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 00:28:11

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:28:11

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 00:28:11

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 00:28:11

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

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**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 00:28:11

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:28:11



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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:28:11

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 00:28:11



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Folder: New Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 00:28:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 00:28:11



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:28:11



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 00:28:11



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 00:28:11



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:28:11



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 00:28:11



US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:58:52

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:28:11

**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 00:28:11



**US3522274**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 07:58:52**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:28:11
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 00:28:11

US3522274

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:58:52

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-03-16T14:15:14-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c41e3127-8fe8-40a4-acb2-cc666a30416f'	System	16 Mar 2021 18:15:25
User entered 'No (N)'	System	16 Mar 2021 18:15:25

US3522274

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:58:52

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:04:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (627CB4A0-4B6D-4E27-B6AE-8F67B6F5EF61)', Time: '2021-03-16T14:15:18-04:00', User OID: 'PatientReportedOutcome (US3522274)', ODM File OID: 'c41e3127-8fe8-40a4-acb2-cc666a30416f'	System	16 Mar 2021 18:15:25
User entered '16 Mar 2021 14:15:18'	System	16 Mar 2021 18:15:25

US3522274

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	18 Nov 2020 15:46:13

US3522274

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
User entered '19 Nov 2020' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	19 Nov 2020 21:31:38
User entered '18 Nov 2020'	Yaman Ahmed (b) (4) (b) (4)	18 Nov 2020 15:46:13

US3522274

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	(b) (4) Yaman Ahmed (b) (4)	19 Nov 2020 21:31:38
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yaman Ahmed (b) (4) (b) (4)	18 Nov 2020 15:46:13

US3522274

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure' reason for change: New Information	(b) (4) Yaman Ahmed (b) (4)	19 Nov 2020 21:31:38
User entered 'left a voicemail'	Yaman Ahmed (b) (4)	18 Nov 2020 15:46:13

US3522274

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	19 Nov 2020 21:31:43



US3522274

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 20:49:31
User entered 'I'	System	19 Nov 2020 21:31:43

US3522274

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	22 Dec 2020 16:44:34

US3522274

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '22 Dec 2020'	(b) (4) Yaman Ahmed (b) (4)	22 Dec 2020 16:44:34

US3522274

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Yaman Ahmed (b) (4)	22 Dec 2020 16:44:34

US3522274

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No ongoing or new AE reported, no new illness or hospital visits; no changes in health status, medications, Covid-19 exposure'	Yaman Ahmed (b) (4)	22 Dec 2020 16:44:34

US3522274

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) Yaman Ahmed (b) (4)	22 Dec 2020 16:44:39

US3522274

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User entered 'I'	System	22 Dec 2020 16:44:39

US3522274

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	21 Jan 2021 15:29:35



US3522274

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '19 Jan 2021'	(b) (4) Yaman Ahmed (b) (4)	21 Jan 2021 15:29:35

US3522274

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
User entered 'Contact Made (CONTACT MADE)'	Yaman Ahmed (b) (4) (b) (4)	21 Jan 2021 15:29:35

US3522274

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'merged with OL visit'	(b) (4) Yaman Ahmed (b) (4)	21 Jan 2021 15:29:35

US3522274

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	21 Jan 2021 15:29:43

US3522274

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User entered '1'	System	21 Jan 2021 15:29:43

US3522274

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 15:21:08

US3522274

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
User entered '18 Feb 2021'	Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 15:21:08

US3522274

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
User entered 'Contact Made (CONTACT MADE)'	Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 15:21:08



US3522274

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User closed query 'Per DM CLR: Review specified comment, HE HAD TO GO TO THE HOSPITAL YESTERDAY, 17 FEB 2021 (UNIVERSITY OF MICHIGAN) FOR WORSENING CHEST PAIN (SINCE LAST WEEK) AND NEW-ONSET SOB. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Marcus Zervos (b) (4)	08 Mar 2021 11:33:56 05 Mar 2021 15:43:53
Query 'Per DM CLR: Review specified comment, HE HAD TO GO TO THE HOSPITAL YESTERDAY, 17 FEB 2021 (UNIVERSITY OF MICHIGAN) FOR WORSENING CHEST PAIN (SINCE LAST WEEK) AND NEW-ONSET SOB. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' answered with 'AE page updated' (Site from DM). User opened query 'Per DM CLR: Review specified comment, HE HAD TO GO TO THE HOSPITAL YESTERDAY, 17 FEB 2021 (UNIVERSITY OF MICHIGAN) FOR WORSENING CHEST PAIN (SINCE LAST WEEK) AND NEW-ONSET SOB. Verify if this condition meets AE reporting criteria per protocol 8.3.6. If yes, update AE page as appropriate. Else, provide clarification. ' (Site from DM).	Sharon Mathys (b) (4)	05 Mar 2021 14:34:08
User entered 'Did not make it for OL Dose2 appointment as he had to go to the hospital yesterday, 17 Feb 2021 (university of Michigan) for worsening chest pain (since last week) and new-onset SOB'	Yaman Ahmed (b) (4)	18 Feb 2021 15:21:08

US3522274

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 15:21:15

US3522274

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:32:10
User entered '1'	System	18 Feb 2021 15:21:15

US3522274

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:36

US3522274

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System). User signature succeeded.	(b) (4), (b) (6)	17 Apr 2021 11:45:08
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'after hospitalization' (Site from System).	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	09 Apr 2021 15:46:44
User entered '9 Apr 2021'	(b) (4), (b) (6)	09 Apr 2021 15:46:36

US3522274

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:36

US3522274

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

[Folder OID](#)

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Audit	User	Time (GMT)
User entered 'VISIT4'	System	09 Apr 2021 15:46:36

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US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:51:18



US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:51:18

US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '11:14'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:51:18

US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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

---

Audit	User	Time (GMT)
User entered '9 Apr 2021 11:14'	System	09 Apr 2021 15:51:18

---

US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:51:18

US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:51:18

US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:51:18

US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '65'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:51:18

US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 15:51:18

---



US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '20'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:51:18

US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 15:51:18

US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '106'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:51:18

US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 15:51:18

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US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '64'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:51:18

US3522274

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:58:52

[Diastolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 15:51:18

---

US3522274

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:50

US3522274

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:50



US3522274

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:58

US3522274

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:58

US3522274

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '11:25'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:58

US3522274

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

[Collection date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '9 Apr 2021 11:25'	System	09 Apr 2021 15:46:58

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US3522274

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:47:03

US3522274

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 15:47:03

---

US3522274

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	22 Apr 2021 16:11:39
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	22 Apr 2021 14:25:30

US3522274

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:11:39
User entered '22 Apr 2021'	(b) (4) Yaman Ahmed (b) (4)	22 Apr 2021 14:25:30
	(b) (4)	



US3522274

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:36:22
Signature has been broken.	(b) (4)	
	Yaman Ahmed (b) (4)	22 Apr 2021 18:09:46
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)' reason for change: New Information	Yaman Ahmed (b) (4)	22 Apr 2021 18:09:46
	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:11:39
	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Yaman Ahmed (b) (4)	22 Apr 2021 14:25:30
	(b) (4)	

US3522274

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:36:22
Signature has been broken.	(b) (4)	
	Yaman Ahmed (b) (4)	22 Apr 2021 18:09:46
	(b) (4)	
User entered 'see source doc for details' reason for change: New Information	Yaman Ahmed (b) (4)	22 Apr 2021 18:09:46
	(b) (4)	
User signature succeeded.	Marcus Zervos (b) (4)	22 Apr 2021 16:11:39
	(b) (4)	
User entered 'left a voicemail message'	Yaman Ahmed (b) (4)	22 Apr 2021 14:25:30
	(b) (4)	

US3522274

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	26 Apr 2021 12:36:22
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	22 Apr 2021 18:09:51

US3522274

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

---

Audit	User	Time (GMT)
User entered '1'	System	22 Apr 2021 18:09:51

---

US3522274

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

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:08:17

US3522274

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

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:08:17

US3522274

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

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:08:17

US3522274

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

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 19:08:17



US3522274

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:52

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:08:28

US3522274

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:52

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:11:42
User entered '0'	(b) (4) Sharon Mathys (b) (4)	17 Mar 2021 12:16:25
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 06:12:11

US3522274

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:52

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:08:28

US3522274

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:52

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:11:42
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4) Sharon Mathys (b) (4)	17 Mar 2021 12:16:25
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 06:12:11

US3522274

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:52

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:08:28

US3522274

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:52

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:08:28

US3522274

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:52

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 07:58:57
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 19:08:28

US3522274

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:52

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 07:58:57
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	19 Jan 2021 19:08:28



US3522274

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:52

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:08:28

US3522274

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:52

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered '1'	System	19 Jan 2021 19:08:28

US3522274

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

Form: Unblinding

Generated On: 10 Jun 2021 07:58:52

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered '1'	System	19 Jan 2021 19:08:28

US3522274

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	19 Jan 2021 19:56:11
DataPoint set to visible.	System	19 Jan 2021 19:08:28

US3522274

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11



US3522274

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	19 Jan 2021 19:56:11
DataPoint set to visible.	System	19 Jan 2021 19:08:28

US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User accepted default value 'Pre-Dose (PREDOSE)'		19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '14:12'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered '19 Jan 2021 14:12'	System	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11



US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '60'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'bpm'	System	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '17'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'breaths/min'	System	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '154'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'mmHg'	System	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '63'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11



US3522274

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

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'mmHg'	System	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:58:52

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered empty.	System	19 Jan 2021 19:56:11
DataPoint set to visible.	System	19 Jan 2021 19:08:28

US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '14:53'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11



US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered '19 Jan 2021 14:53'	System	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '58'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'bpm'	System	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '17'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'breaths/min'	System	19 Jan 2021 19:56:11



US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '157'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'mmHg'	System	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '68'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:56:11

US3522274

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

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'mmHg'	System	19 Jan 2021 19:56:11

US3522274

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

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:24:50

US3522274

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

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:24:50

US3522274

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

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:25:02

US3522274

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

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:25:02



US3522274

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

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:25:02

US3522274

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

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'mRNA-1273'	System	19 Jan 2021 19:25:02
DataPoint set to visible.	System	19 Jan 2021 19:08:28

US3522274

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

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:25:02

US3522274

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

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '14:22'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:25:02

US3522274

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

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered '19 Jan 2021 14:22'	System	19 Jan 2021 19:25:02

US3522274

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

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:25:02

US3522274

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

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'ONCE'	System	19 Jan 2021 19:25:02

US3522274

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

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 19:25:02



US3522274

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:24:28

US3522274

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:24:28

US3522274

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '14:16'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:24:28

US3522274

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:58:52

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered '19 Jan 2021 14:16'	System	19 Jan 2021 19:24:28

US3522274

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:58:52

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:24:38

US3522274

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:58:52

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '19 Jan 2021'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:24:38

US3522274

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:58:52

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '14:18'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:24:38

US3522274

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:58:52

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered '19 Jan 2021 14:18'	System	19 Jan 2021 19:24:38



US3522274

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

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:24:42

US3522274

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

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:46:15
User entered '1'	System	19 Jan 2021 19:24:42

US3522274

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:55:00

US3522274

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:55:00

US3522274

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:55:00

US3522274

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User closed query 'Per DM CLR: Please review if ARM SORENESS is considered an AE event and should be recorded in AE ecrf. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 03:27:12
Query 'Per DM CLR: Please review if ARM SORENESS is considered an AE event and should be recorded in AE ecrf. Review and update as appropriate. ' answered with 'Is not a reportable AE (MAAE or SAE)' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	26 Feb 2021 19:16:48
User opened query 'Per DM CLR: Please review if ARM SORENESS is considered an AE event and should be recorded in AE ecrf. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 15:48:06
User entered 'Reports arm soreness for 2 days with resolution, denies any other AEs. No new illness or hospital visits; no changes in health status, medications, Covid-19 exposure or pregnancy risk'	(b) (4), (b) (6)	26 Jan 2021 15:55:00

US3522274

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:09
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 16:00:06

US3522274

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:09
User entered '1'	System	26 Jan 2021 16:00:06



US3522274

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:05:09
User entered '1'	System	26 Jan 2021 16:00:06
DataPoint set to visible.	System	26 Jan 2021 16:00:06

US3522274

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:45:44

US3522274

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 09:29:23
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'participant dosed after hospitalization' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:45:54
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	09 Apr 2021 15:45:44
User entered '9 Apr 2021'	(b) (4), (b) (6)	09 Apr 2021 15:45:44

US3522274

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:45:44

US3522274

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:58:52

[Folder OID](#)

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Audit	User	Time (GMT)
User entered 'OLD29'	System	09 Apr 2021 15:45:44

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US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25



US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '11:14'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

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

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Audit	User	Time (GMT)
User entered '9 Apr 2021 11:14'	System	09 Apr 2021 16:23:25

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US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '97.8' F	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '65'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 16:23:25

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US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '20'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25



US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Respiratory Rate units](#)

---

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 16:23:25

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US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '106'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Systolic Blood Pressure units](#)

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Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 16:23:25

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US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '64'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:58:52

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 16:23:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 16:23:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:23:29
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 16:23:25
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25



US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '11:57'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

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

---

Audit	User	Time (GMT)
User entered '9 Apr 2021 11:57'	System	09 Apr 2021 16:23:25

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US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '98.4' F	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'temporal'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '65'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Pulse units](#)

---

Audit	User	Time (GMT)
User entered 'bpm'	System	09 Apr 2021 16:23:25

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US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '20'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25



US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '96'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

[Systolic Blood Pressure units](#)

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 16:23:25

---

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '74'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:23:25

US3522274

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:58:52

Diastolic Blood Pressure units

---

Audit	User	Time (GMT)
User entered 'mmHg'	System	09 Apr 2021 16:23:25

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US3522274

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:00

US3522274

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:58:52

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:00

US3522274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:14



US3522274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:14

US3522274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

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

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:14

US3522274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	09 Apr 2021 15:46:14
DataPoint set to visible.	System	26 Jan 2021 16:00:06

US3522274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '9 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:14

US3522274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '11:27'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:14

US3522274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[Treatment Date and Time \(derived\)](#)

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Audit	User	Time (GMT)
User entered '9 Apr 2021 11:27'	System	09 Apr 2021 15:46:14

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US3522274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:14

US3522274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	09 Apr 2021 15:46:14



US3522274

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:58:52

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	09 Apr 2021 15:46:14

US3522274

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:46:21

US3522274

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

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Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 15:46:21

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US3522274

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:33:52

US3522274

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:33:52

US3522274

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:33:52

US3522274

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:58:52

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered 'Participant had muscle aches for 14 hours after dose and took tylenol that evening 1000mg. No issues the next day.'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:33:52

US3522274

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:34:01



US3522274

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:58:52

[Continuing Flag](#)

---

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:34:01

---

US3522274

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 07:58:52

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:29
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 215 (30MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:49:07
Query 'Per DM CLR: Per Safety Follow Up Diary Day 215 (30MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'It is included in the time period of the AEs in the log (the SAEs in particular)' (Site from DM).	Sharon Mathys (b) (4) (b) (4)	05 Apr 2021 18:40:03
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 215 (30MAR2021) 'Any changes since last questionnaire or contact with study clinic?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 03:36:51
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)' reason for change: New Information	Yaman Ahmed (b) (4) (b) (4)	18 Feb 2021 15:22:01
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 14:41:49

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:48:40
User entered 'USA-US131-2021-mRNA-1273-P301000009'	System	04 Mar 2021 15:47:21
User entered 'New'	(b) (4), (b) (6)	04 Mar 2021 15:47:21

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 19:53:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 19:53:53
Data point term sent to Coder	System	11 Mar 2021 19:38:05
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ? ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	11 Mar 2021 19:37:55
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 19:37:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Mar 2021 19:37:53
Data point term sent to Coder	System	11 Mar 2021 19:37:04
User entered 'Coronary Artery Disease' reason for change: New Information	(b) (4), (b) (6)	11 Mar 2021 19:36:43
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, NON CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ? ' (Site from System).	Coder Import (b) (4) (b) (4)	09 Mar 2021 18:57:39
Data point term sent to Coder	System	03 Mar 2021 20:28:04
User entered 'Worsening Chest pain'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Feb 2021'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 20:28:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions. ' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:22:27
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:22:10
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	11 Mar 2021 18:39:21
User entered 'Grade 3/Severe (Grade 3/Severe)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03



US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	14 Apr 2021 07:11:29
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 with 'reviewed and reconciled. Information can be found in 3/23/2021 office visit-Michigan medicine, U of M, care everywhere note.' (Site from System).	(b) (4), (b) (6)	13 Apr 2021 13:49:28
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	03 Mar 2021 20:28:03
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Feb 2021' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Apr 2021 13:52:19
User entered '17 Feb 2021'	Yaman Ahmed (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the hospital discharge date when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:40:54
User entered '23 Mar 2021' reason for change: New Information	Sharon Mathys (b) (4)	26 Mar 2021 12:58:47
User opened query 'PV Query: Please provide the hospital discharge date when available. ' (Site from Safety).	(b) (4)	
User entered empty.	(b) (4), (b) (6)	10 Mar 2021 14:21:59
	Yaman Ahmed (b) (4)	03 Mar 2021 20:28:03
	(b) (4)	

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 13:51:32
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered '10' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 13:51:32
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03



US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Action taken with study drug provided as "None", but source states the subject did not make it to second visit due to hospitalization, please confirm/update if Action Taken should be update from "None". ' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 13:34:30
Query 'PV Query: Action taken with study drug provided as "None", but source states the subject did not make it to second visit due to hospitalization, please confirm/update if Action Taken should be update from "None". ' answered with 'updated' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 12:01:45
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	11 Mar 2021 18:39:21
User opened query 'PV Query: Action taken with study drug provided as "None", but source states the subject did not make it to second visit due to hospitalization, please confirm/update if Action Taken should be update from "None". ' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:23:00
User entered 'None (NONE)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

None

Audit	User	Time (GMT)
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' canceled (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:41:57
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. ' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:22:51
User entered 'I'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03



US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify hospital admission date two events report admission date as 16 Feb 2021 and the other two report as 17 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:22:35
Query 'PV Query: Please clarify hospital admission date two events report admission date as 16 Feb 2021 and the other two report as 17 Feb 2021.' answered with 'Actual admission date was 16 feb. Had not been updated as initial contact with patient gave the wrong admission date.' (Site from Safety).	Sharon Mathys (b) (4)	29 Apr 2021 13:55:27
User entered 'From safety call: DID NOT MAKE IT FOR OL DOSE2 APPOINTMENT AS HE HAD TO GO TO THE HOSPITAL FOR WORSENING CHEST PAIN (SINCE LAST WEEK) AND NEW-ONSET SOB. Reported going on 17 feb 2021 but hospital records indicate arrival the night of 16 feb 2021. HE IS NOW WAITING FOR A CORONARY ARTERY BYPASS (MAJOR ARTERY BIFURCATION) TOMORROW (19 FEB 2021) OR ON SATURDAY (20 FEB 2021). HE HAS A HISTORY OF EXERTIONAL CHEST PAIN AND HIGH BLOOD PRESSURE, BUT DIDN'T THINK MUCH OF IT UNTIL LAST WEEK'S CHANGES. CHART CHECKED ON MARCH 11TH. PARTICIPANT IS STILL ADMITTED AT THIS TIME. PARTICIPANT POST CABG AND AORTIC VALVE REPLACEMENT. PATIENT FOUND TO HAVE PLEURAL EFFUSION AND HAD FLUID 300ML OF FLUID ASPIRATED UNDER ULTRASOUND GUIDANCE ON 3/10/21. RENAL LABS ARE ELEVATED AT THIS TIME. SOME ABNORMALITIES IN REGULAR DAILY BLOOD WORK. PARTICIPANT HAD NEGATIVE COVID SWAB ON 3/6/21. HAD IMAGING DONE ON 3/10/21 AND FOUND TO HAVE DEEP VEIN THROMBOSIS BILATERALLY IN SEVERAL VEINS.' reason for change: New Information	Sharon Mathys (b) (4)	29 Apr 2021 13:53:45
User opened query 'PV Query: Please clarify hospital admission date two events report admission date as 16 Feb 2021 and the other two report as 17 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:26:47

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative indicates that the subject had Coronary Artery Bypass Graft and Aortic Valve Replacement. However, there are no recorded Concomitant Procedures record that match the information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 04:54:58
Query 'Per DM CLR: Narrative indicates that the subject had Coronary Artery Bypass Graft and Aortic Valve Replacement. However, there are no recorded Concomitant Procedures record that match the information. Please update to record the procedures as appropriate. Otherwise, clarify.' answered with 'added' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 15:37:18
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)	05 Apr 2021 13:20:03
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 'Discharge, labs and results have been sent' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	02 Apr 2021 15:26:19
User opened query 'Per DM CLR: Narrative indicates that the subject had Coronary Artery Bypass Graft and Aortic Valve Replacement. However, there are no recorded Concomitant Procedures record that match the information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 20:52:01
User closed query 'PV Query: per report of "history of exertional chest pain" please consider adding as medical history' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 17:28:28

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Narrative](#)

Audit	User	Time (GMT)
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)	29 Mar 2021 17:28:24
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 'COVID-19 Testing using nasopharyngeal swab done 16 feb 2021, 23 feb 2021, 01 mar 2021, 6 mar 2021, 22 mar 2021 by PCR . All tests negative. Will be sent with other laboratory results.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	26 Mar 2021 13:04:34
Query 'PV Query: per report of "history of exertional chest pain" please consider adding as medical history' answered with 'Added with an unknown start and ongoing as participant could not disclose when this happened. This does not come with a diagnosis, only self reported by participant.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	26 Mar 2021 13:02:16
User entered 'DID NOT MAKE IT FOR OL DOSE2 APPOINTMENT AS HE HAD TO GO TO THE HOSPITAL YESTERDAY, 17 FEB 2021 (UNIVERSITY OF MICHIGAN) FOR WORSENING CHEST PAIN (SINCE LAST WEEK) AND NEW-ONSET SOB. HE IS NOW WAITING FOR A CORONARY ARTERY BYPASS (MAJOR ARTERY BIFURCATION) TOMORROW (19 FEB 2021) OR ON SATURDAY (20 FEB 2021). HE HAS A HISTORY OF EXERTIONAL CHEST PAIN AND HIGH BLOOD PRESSURE, BUT DIDN'T THINK MUCH OF IT UNTIL LAST WEEK'S CHANGES. Chart checked on March 11th. Participant is still admitted at this time. Participant post CABG and Aortic valve replacement. Patient found to have pleural effusion and had fluid 300ml of fluid aspirated under ultrasound guidance on 3/10/21. Renal labs are elevated at this time. Some abnormalities in regular daily blood work. Participant had negative covid swab on 3/6/21. Had imaging done on 3/10/21 and found to have deep vein thrombosis bilaterally in several veins.' reason for change: New Information	(b) (4), (b) (6)	11 Mar 2021 19:14:35

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: per report of "history of exertional chest pain" please consider adding as medical history' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 14:23:13
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)	10 Mar 2021 14:21:40
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)	10 Mar 2021 14:21:20
User entered 'Did not make it for OL Dose2 appointment as he had to go to the hospital yesterday, 17 Feb 2021 (university of Michigan) for worsening chest pain (since last week) and new-onset SOB. He is now waiting for a coronary artery bypass (major artery bifurcation) tomorrow (19 Feb 2021) or on Saturday (20 Feb 2021). He has a history of exertional chest pain and high blood pressure, but didn't think much of it until last week's changes.'	Yaman Ahmed (b) (4)	03 Mar 2021 20:28:03

US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	03 Mar 2021 20:28:03

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US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	03 Mar 2021 20:28:03

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US3522274

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:58:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 13:51:32

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US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:49:12
User entered 'USA-US131-2021-mRNA-1273-P301000009'		04 Mar 2021 15:49:06



US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Feb 2021'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03



US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[AE start date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 20:29:03

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US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:42:31
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 20:29:03

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US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

Death

Audit	User	Time (GMT)
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03



US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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).	System	29 Apr 2021 13:56:34
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).	System	29 Apr 2021 13:56:34
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	03 Mar 2021 20:29:03
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Feb 2021' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Mar 2021 12:56:24
User entered '17 Feb 2021' reason for change: Data Entry Error	Yaman Ahmed (b) (4)	03 Mar 2021 20:30:12
User entered empty.	Yaman Ahmed (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Mar 2021' reason for change: New Information	Sharon Mathys (b) (4)	26 Mar 2021 12:56:24
User entered empty.	Yaman Ahmed (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	29 Apr 2021 13:56:34
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered '10' reason for change: New Information	Sharon Mathys (b) (4) (b) (4)	29 Apr 2021 13:56:34
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03



US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 12:02:02
User entered 'None (NONE)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

None

Audit	User	Time (GMT)
User entered '0'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:39:10
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).		05 Apr 2021 21:42:45
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify hospital admission date two events report admission date as 16 Feb 2021 and the other two report as 17 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:22:41
Query 'PV Query: Please clarify hospital admission date two events report admission date as 16 Feb 2021 and the other two report as 17 Feb 2021.' answered with 'clarified to 16 feb 2021. Older reports were from participant response as notes were not yet available and intake date was not correctly communicated to staff.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	29 Apr 2021 13:57:51
User entered 'DID NOT MAKE IT FOR OL DOSE2 APPOINTMENT AS HE HAD TO GO TO THE HOSPITAL 16 FEB 2021 (UNIVERSITY OF MICHIGAN) FOR WORSENING CHEST PAIN (SINCE LAST WEEK) AND NEW-ONSET SOB. HE IS NOW WAITING FOR A CORONARY ARTERY BYPASS (MAJOR ARTERY BIFURCATION) TOMORROW (19 FEB 2021) OR ON SATURDAY (20 FEB 2021). HE HAS A HISTORY OF EXERTIONAL CHEST PAIN AND HIGH BLOOD PRESSURE, BUT DIDN'T THINK MUCH OF IT UNTIL LAST WEEK'S CHANGES.' reason for change: Per Query Resolution	Sharon Mathys (b) (4) (b) (4)	29 Apr 2021 13:57:08
User opened query 'PV Query: Please clarify hospital admission date two events report admission date as 16 Feb 2021 and the other two report as 17 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:27:07
User entered 'Did not make it for OL Dose2 appointment as he had to go to the hospital yesterday, 17 Feb 2021 (university of Michigan) for worsening chest pain (since last week) and new-onset SOB. He is now waiting for a coronary artery bypass (major artery bifurcation) tomorrow (19 Feb 2021) or on Saturday (20 Feb 2021). He has a history of exertional chest pain and high blood pressure, but didn't think much of it until last week's changes.'	Yaman Ahmed (b) (4) (b) (4)	03 Mar 2021 20:29:03

US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

Serious Adverse Event Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	03 Mar 2021 20:29:03

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US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	03 Mar 2021 20:29:03

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US3522274

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:58:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 13:56:34

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US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 18:50:38
User entered 'USA-US131-2021-mRNA-1273-P301000009'		12 Mar 2021 18:44:05

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM: Please update the AE term to specify cause or medical diagnosis.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 14:07:01
Query 'Per MM: Please update the AE term to specify cause or medical diagnosis.' answered with 'Please clarify? Pleural effusion is a medical diagnosis' (Site from DM).	Sharon Mathys (b) (4)	09 Apr 2021 14:58:41
User opened query 'Per MM: Please update the AE term to specify cause or medical diagnosis.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:59:36
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pleural effusion - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 19:55:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Mar 2021 19:55:52
Data point term sent to Coder System	System	11 Mar 2021 19:40:07
User entered 'Pleural Effusion'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 19:39:07



US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Mar 2021'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:44:43
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:44:24
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[AE start date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 19:39:07

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US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query '? PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:44:41
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:39:07



US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 19:39:07

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US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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).	System	29 Apr 2021 13:58:20
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).	System	29 Apr 2021 13:58:20
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	11 Mar 2021 19:39:07
User entered '1'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '16 Feb 2021' reason for change: Data Entry Error	Sharon Mathys (b) (4)	26 Mar 2021 12:55:16
User entered '17 Feb 2021'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Mar 2021' reason for change: New Information	Sharon Mathys (b) (4)	26 Mar 2021 12:55:16
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:39:07



US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Apr 2021 13:58:20
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered '10' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Apr 2021 13:58:20
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4), (b) (6)	11 Mar 2021 19:39:07



US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

None

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:39:44
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:43:00
User entered 'Unknown (UNKNOWN)'	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify hospital admission date two events report admission date as 16 Feb 2021 and the other two report as 17 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:22:48
Query 'PV Query: Please clarify hospital admission date two events report admission date as 16 Feb 2021 and the other two report as 17 Feb 2021.' answered with 'clarified to 16 feb 2021. Older reports were from participant response as notes were not yet available and intake date was not correctly communicated to staff.' (Site from Safety).	Sharon Mathys (b) (4) (b) (4)	29 Apr 2021 13:58:03
User opened query 'PV Query: Please clarify hospital admission date two events report admission date as 16 Feb 2021 and the other two report as 17 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:27:27
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	15 Mar 2021 14:56:18
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	15 Mar 2021 14:56:18
User entered 'Pleural Effusion Diagnosed on 10 mar 2021 while in the hospital, originally went for shortness of breath. Not main complaint at this time per records able to be seen for 10 mar 2021.' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 14:56:18
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	11 Mar 2021 19:39:07
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:39:07

US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Mar 2021 19:39:07

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US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Mar 2021 19:39:07

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US3522274

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 07:58:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 13:58:20

---

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 18:50:38
User entered 'USA-US131-2021-mRNA-1273-P301000009'	(b) (4), (b) (6)	12 Mar 2021 18:44:58

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLT: Peripheral embolism and thrombosis, PT: Deep vein thrombosis, LLT: Deep vein thrombosis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 19:43:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Mar 2021 19:43:08
Data point term sent to Coder	System	11 Mar 2021 19:42:10
User entered 'Bilateral Deep Vein thrombosis'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Mar 2021'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:41:22



US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[AE start date and time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 19:41:22

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US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:45:06
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[AE End Date and Time \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	11 Mar 2021 19:41:22

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US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

Death

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 19:41:22



US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Life threatening](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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).	System	26 Mar 2021 12:54:33
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).	System	26 Mar 2021 12:54:33
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	11 Mar 2021 19:41:22
User entered '1'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '16 Feb 2021' reason for change: Data Entry Error	Sharon Mathys (b) (4)	29 Apr 2021 13:59:48
User entered '17 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 19:49:39
User entered empty.		11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '23 Mar 2021' reason for change: New Information	Sharon Mathys (b) (4)	26 Mar 2021 12:54:33
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	15 Mar 2021 14:49:53
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		15 Mar 2021 14:49:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	15 Mar 2021 14:49:53
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	11 Mar 2021 19:41:22
User entered 'Unknown (UNK)'	(b) (4), (b) (6) (b) (4)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	29 Apr 2021 13:59:48
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).	System	29 Apr 2021 13:59:48
User entered '10' reason for change: Data Entry Error	Sharon Mathys (b) (4) (b) (4)	29 Apr 2021 13:59:48
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	15 Mar 2021 14:49:53
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 19:41:22



US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

Action taken with investigational product

Audit	User	Time (GMT)
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[None](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:40:16
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 21:45:26
User entered 'Unknown (UNKNOWN)'	(b) (4), (b) (6)	11 Mar 2021 19:41:22



US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify hospital admission date two events report admission date as 16 Feb 2021 and the other two report as 17 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:22:55
Query 'PV Query: Please clarify hospital admission date two events report admission date as 16 Feb 2021 and the other two report as 17 Feb 2021.' answered with 'clarified to 16 feb 2021. Older reports were from participant response as notes were not yet available and intake date was not correctly communicated to staff.' (Site from Safety).	Sharon Mathys (b) (4)	29 Apr 2021 13:59:59
User opened query 'PV Query: Please clarify hospital admission date two events report admission date as 16 Feb 2021 and the other two report as 17 Feb 2021.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 17:28:15
User entered 'The following RIGHT-sided veins revealed evidence of ACUTE DEEP VENOUS THROMBOSIS (DVT): mid posterior tibial vein (totally occluding); distal posterior tibial vein (totally occluding); proximal peroneal vein (totally occluding); mid peroneal vein (totally occluding); distal peroneal vein (totally occluding); soleal vein (totally occluding); · The following RIGHT-sided veins revealed evidence of ACUTE SUPERFICIAL THROMBOSIS: great saphenous vein (partially occluding) less than 5 cm; · The following LEFT-sided veins revealed evidence of ACUTE DEEP VENOUS THROMBOSIS (DVT): prox peroneal vein (totally occluding); mid peroneal vein (totally occluding); distal peroneal vein (totally occluding); soleal vein (totally occluding);'	(b) (4), (b) (6)	11 Mar 2021 19:41:22

US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

Serious Adverse Event Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Mar 2021 19:41:22

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US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

Medically Attended AE Derived (CSA Programming Field Only)

---

Audit	User	Time (GMT)
User entered '1'	System	11 Mar 2021 19:41:22

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US3522274

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 07:58:52

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Mar 2021 14:49:53
User entered '0'	System	11 Mar 2021 19:41:22

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:58:52

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:29
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:51:41

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 13:53:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Aug 2020 13:53:53
Data point term sent to Coder	System	26 Aug 2020 13:52:41
User entered 'Losartan'	(b) (4), (b) (6)	26 Aug 2020 13:52:09

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:52:09



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:52:09

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '100'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:52:09

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:52:09

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:52:09

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:52:09

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:52:09

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:52:09

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:52:09



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:52:09

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:52:09

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 15:44:37
User entered 'No (N)' reason for change: Data Entr Error	(b) (4), (b) (6)	09 Apr 2021 15:44:37
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 13:52:09

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:56:25
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	09 Apr 2021 15:44:37
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	09 Apr 2021 15:44:24
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 15:44:24
User entered '19 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 15:44:24
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:52:09

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:52:09

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User entered '1'	System	26 Aug 2020 13:52:09

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:58:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User entered '1'	System	26 Aug 2020 13:52:09

US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:03:26
User entered '804 (804)'	System	26 Aug 2020 13:52:09



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: MIRTAZAPINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	26 Aug 2020 14:55:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 14:55:43
Data point term sent to Coder	System	26 Aug 2020 13:53:44
User entered 'Mirtazapine'	(b) (4), (b) (6)	26 Aug 2020 13:53:12

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:53:12

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Anxiety and Depression'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:53:12

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '15'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:53:12

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:53:12

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:53:12

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:53:12

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:53:12



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:53:12

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:53:12

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:53:12

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:53:12

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:53:12

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:53:12

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:58:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	26 Aug 2020 13:53:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Aug 2020 13:53:37
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	26 Aug 2020 13:53:37
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 13:53:12
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 13:53:12

US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:58:52**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 13:53:12

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 13:53:12

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 13:53:12

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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: 8-TETRAHYDROCANNABINOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	24 Nov 2020 12:06:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:06:09
Data point term sent to Coder	System	09 Oct 2020 17:31:17
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	09 Oct 2020 17:30:49
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	09 Oct 2020 17:30:49
User entered 'tetrahydrocannabinol' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Oct 2020 17:30:43
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	11 Sep 2020 11:36:31
Data point term sent to Coder	System	26 Aug 2020 13:56:53
User entered 'THC'	(b) (4), (b) (6)	26 Aug 2020 13:56:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Anxiety'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '5'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:23



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:23



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:58:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:23

US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:52**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 13:56:23

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	26 Aug 2020 13:56:23

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Aug 2020 13:56:23

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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Sep 2020 15:02:30
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: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 05:14:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Sep 2020 05:14:42
Data point term sent to Coder	System	08 Sep 2020 05:13:39
User entered 'Omeprazole' reason for change: Data Entry Error	mayur ramesh (b) (4)	08 Sep 2020 05:13:18
Data point term sent to Coder	System	08 Sep 2020 05:12:38
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4)	08 Sep 2020 05:12:29
Data point term sent to Coder	System	08 Sep 2020 05:10:37
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4)	08 Sep 2020 05:09:41
User closed query 'DM-Coding: Please add active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	08 Sep 2020 05:08:23
Query 'DM-Coding: Please add active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'error' (Site from System).	mayur ramesh (b) (4)	08 Sep 2020 05:08:23
Query 'Data is required. Please complete.' answered with 'error' (Site from System).	mayur ramesh (b) (4)	08 Sep 2020 05:08:16
Data point term sent to Coder	System	08 Sep 2020 05:07:36
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 05:07:12
User entered empty; reason for change Data Entry Error	mayur ramesh (b) (4)	08 Sep 2020 05:07:12
User opened query 'DM-Coding: Please add active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	26 Aug 2020 18:51:26
Data point term sent to Coder	System	26 Aug 2020 13:57:54

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'CBD'	(b) (4), (b) (6)	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Sep 2020 15:02:07
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4)	08 Sep 2020 05:13:18
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Sep 2020 05:12:29
Query 'Data is required. Please complete.' answered with 'error' (Site from System).	mayur ramesh (b) (4)	08 Sep 2020 05:09:41
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Sep 2020 05:08:14
User entered empty; reason for change Data Entry Error	System	08 Sep 2020 05:07:12
User entered 'No (N)'	mayur ramesh (b) (4)	08 Sep 2020 05:07:12
	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:02:09
User entered 'GERD' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:13:18
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:12:29
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:09:41
Query 'Data is required. Please complete.' answered with 'error' (Site from System).	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:08:12
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 05:07:12
User entered empty; reason for change Data Entry Error	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:07:12
User entered 'Anxiety'	(b) (4), (b) (6)	26 Aug 2020 13:56:55



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:02:12
User entered '20' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:13:18
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:12:29
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:09:41
Query 'Data is required. Please complete.' answered with 'error' (Site from System).	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:08:11
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 05:07:12
User entered empty; reason for change Data Entry Error	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:07:12
User entered '5'	(b) (4), (b) (6)	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:02:15
User entered 'mg (mg)' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:13:18
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:12:29
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:09:41
Query 'Data is required. Please complete.' answered with 'error' (Site from System).	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:08:08
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 05:07:12
User entered empty; reason for change Data Entry Error	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:07:12
User entered 'mg (mg)'	(b) (4), (b) (6)	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:12:29
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:09:41
User entered empty.	(b) (4), (b) (6) (b) (4)	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Sep 2020 15:02:17
User entered 'once daily (QD)' reason for change: Data Entry Error	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4)	08 Sep 2020 05:13:18
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Sep 2020 05:12:29
Query 'Data is required. Please complete.' answered with 'error' (Site from System).	mayur ramesh (b) (4)	08 Sep 2020 05:09:41
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Sep 2020 05:08:05
User entered empty; reason for change Data Entry Error	System	08 Sep 2020 05:07:12
User entered 'once daily (QD)'	mayur ramesh (b) (4)	08 Sep 2020 05:07:12
	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:12:29
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:09:41
User entered empty.	(b) (4), (b) (6) (b) (4)	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Sep 2020 15:02:19
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4)	08 Sep 2020 05:13:18
DataPoint inactivated with code reason code Data not required.	(b) (4)	08 Sep 2020 05:12:29
Query 'Data is required. Please complete.' answered with 'error' (Site from System).	mayur ramesh (b) (4)	08 Sep 2020 05:09:41
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	08 Sep 2020 05:07:55
User entered empty; reason for change Data Entry Error	System	08 Sep 2020 05:07:12
User entered 'Oral (ORAL)'	mayur ramesh (b) (4)	08 Sep 2020 05:07:12
	(b) (4)	
	(b) (4), (b) (6)	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:12:29
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:09:41
User entered empty.	(b) (4), (b) (6) (b) (4)	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	08 Sep 2020 05:13:18
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4)	08 Sep 2020 05:12:29
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4)	08 Sep 2020 05:09:41
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	08 Sep 2020 05:07:12
User entered empty.	(b) (4), (b) (6)	26 Aug 2020 13:56:55



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
User entered '1' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:13:18
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:12:29
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:09:41
User entered '0' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:07:12
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:02:23
User entered 'Yes (Y)' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:13:18
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:12:29
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:09:41
Query 'Data is required. Please complete.' answered with 'error' (Site from System).	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:08:54
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 05:07:12
User entered empty; reason for change Data Entry Error	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:07:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	05 Mar 2021 15:43:53
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:12:29
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:09:41
User entered empty.	(b) (4), (b) (6) (b) (4)	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:02:25
User entered 'No (N)' reason for change: Data Entry Error	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:13:18
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:12:29
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:09:41
Query 'Data is required. Please complete.' answered with 'error' (Site from System).	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:09:01
User opened query 'Data is required. Please complete.' (Site from System).	System	08 Sep 2020 05:07:12
User entered empty; reason for change Data Entry Error	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:07:12
User entered 'No (N)'	(b) (4), (b) (6)	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 05:13:18
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:12:29
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:09:41
User entered empty.	System	08 Sep 2020 05:07:12
User entered '1'	System	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Sep 2020 05:13:18
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:12:29
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:09:41
User entered empty.	System	08 Sep 2020 05:07:12
User entered '1'	System	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:58:52

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Sep 2020 05:13:18
DataPoint activated with code reason code Data required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:12:29
DataPoint inactivated with code reason code Data not required.	mayur ramesh (b) (4) (b) (4)	08 Sep 2020 05:09:41
User entered empty.	System	08 Sep 2020 05:07:12
User entered '804 (804)'	System	26 Aug 2020 13:56:55

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 15:56:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:56:53
Data point term sent to Coder User entered 'Aspirin'	System (b) (4), (b) (6)	09 Apr 2021 15:55:17 09 Apr 2021 15:54:19



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:54:19

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'cardioprotective'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:54:19

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '81'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:54:19

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:54:19

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:54:19

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:54:19

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:54:19

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:54:19



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:54:19

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '03 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:54:19

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:54:19

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:54:19

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
	(b) (4)	
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	09 Apr 2021 16:16:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:16:49
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	09 Apr 2021 15:54:19
User entered '03 Apr 2021'	(b) (4), (b) (6)	09 Apr 2021 15:54:19

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:58:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:54:19

US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:58:52**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 15:54:19

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 15:54:19

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 15:54:19

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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 07:23:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:23:56
Data point term sent to Coder	System	09 Apr 2021 15:56:18
User entered 'furosemide'	(b) (4), (b) (6)	09 Apr 2021 15:55:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:55:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'cardiac issues'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:55:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '20'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:55:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:55:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:55:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:55:23



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:55:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:55:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:55:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '3 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:55:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:55:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:55:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:55:23

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:58:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:55:23



US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:58:52**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 15:55:23

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 15:55:23

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 15:55:23

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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Apr 2021 15:57:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:57:35
Data point term sent to Coder	System	09 Apr 2021 15:56:19
User entered 'lisinopril'	(b) (4), (b) (6)	09 Apr 2021 15:56:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '2.5'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:00



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '3 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:00



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:58:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:00

US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:58:52**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 15:56:00

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 15:56:00

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 15:56:00

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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Apr 2021 15:58:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 15:58:58
Data point term sent to Coder	System	09 Apr 2021 15:57:20
User entered 'Metoprolol Tartrate'	(b) (4), (b) (6)	09 Apr 2021 15:56:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:45



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '12.5'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '3 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:45



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:58:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:56:45

US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:52**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '2'	System	09 Apr 2021 15:56:45

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 15:56:45

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 15:56:45

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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 16:19:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:19:41
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	09 Apr 2021 16:18:11 09 Apr 2021 16:17:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:13:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:13:35
Data point term sent to Coder User entered 'Miralax'	System (b) (4), (b) (6)	09 Apr 2021 16:12:56 09 Apr 2021 16:12:03



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:12:03

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'prophylaxis for constipation'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:12:03

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '17'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:12:03

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:12:03

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:12:03

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:12:03

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:12:03

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Apr 2021 16:17:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 16:17:18
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:17:18
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 16:12:03
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 16:12:03



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:12:03

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '3 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:12:03

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:12:03

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:12:03

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:12:03

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:58:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:12:03

US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:52**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 16:12:03

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 16:12:03

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 16:12:03

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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 07:48:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:48:50
Data point term sent to Coder	System	09 Apr 2021 16:15:04
User entered 'Warfarin'	(b) (4), (b) (6)	09 Apr 2021 16:14:33

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	09 Apr 2021 16:17:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Apr 2021 16:17:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 16:17:26
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Apr 2021 16:14:33
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 16:14:33

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'cardiac issues'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:14:33

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '3'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:14:33

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:14:33

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:14:33

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:14:33



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:14:33

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:14:33

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:14:33

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '2 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:14:33

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:14:33

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:14:33

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:14:33

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:58:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:14:33



US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:58:52**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 16:14:33

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 16:14:33

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 16:14:33

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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 07:15:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:15:51
Data point term sent to Coder	System	09 Apr 2021 16:16:08
User entered 'Ferrous sulfate'	(b) (4), (b) (6)	09 Apr 2021 16:15:16

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:15:16

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'prophylactic electrolyte'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:15:16

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '325'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:15:16

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:15:16



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:15:16

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:15:16

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:15:16

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:15:16

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:15:16

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '3 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:15:16

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:15:16

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:17:36
User entered 'No (N)'	(b) (4), (b) (6)	09 Apr 2021 16:15:16



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).	(b) (4)	09 Apr 2021 16:17:36
User opened query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		09 Apr 2021 16:15:16
User entered empty.	(b) (4), (b) (6)	09 Apr 2021 16:15:16

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:58:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:15:16

US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:58:52**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 16:15:16

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 16:15:16

---

US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 16:15:16

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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 12:00:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 12:00:52
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	12 Apr 2021 11:56:25
Data point term sent to Coder	System	09 Apr 2021 16:16:08
User entered 'Magnesium Oxide'	(b) (4), (b) (6) (b) (4)	09 Apr 2021 16:16:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:16:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Electrolyte prophylaxis'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:16:00



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '400'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:16:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:16:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:16:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:16:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:16:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:16:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:16:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '3 Apr 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:16:00



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '0'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:16:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:16:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:16:00

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:58:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 16:16:00

US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:58:52**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 16:16:00

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 16:16:00

---

US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 16:16:00

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US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Apr 2021 18:40:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 18:40:13
Data point term sent to Coder	System	16 Apr 2021 18:39:12
User entered 'Tylenol'	(b) (4), (b) (6)	16 Apr 2021 18:38:45



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:38:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered 'Myalgia post dose 2'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:38:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered '1000'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:38:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:38:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:38:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:38:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:38:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:38:45



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:38:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered '09 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:38:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:38:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:38:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered '09 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:38:45

US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Apr 2021 19:03:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 18:38:45

US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:58:52**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:38:45

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US3522274

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 07:58:52**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:38:45

---



US3522274

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 07:58:52

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 18:38:45

---

US3522274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 07:58:52

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:48:29
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:20:57
Signature has been broken.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:49:53
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Mar 2021 19:49:53
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 13:51:33

US3522274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:58:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:20:57
User entered '10 Mar 2021'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:50:12

US3522274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:58:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:20:57
User entered 'Thoracentesis'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:50:12

US3522274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:20:57
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:50:12

US3522274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:58:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:15
User signature succeeded.	Marcus Zervos (b) (4)	12 Mar 2021 15:20:57
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 19:50:12

US3522274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:58:52

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:37:16

US3522274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:58:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Coronary artery bypass and aortic valve replacement'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:37:16



US3522274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:37:16

US3522274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:58:52

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:08
User signature succeeded.	Marcus Zervos (b) (4)	12 Apr 2021 11:56:25
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:37:16

US3522274

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 07:58:52**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:36:22
	(b) (4)	
User entered '13 Apr 2021'	Yaman Ahmed (b) (4)	22 Apr 2021 18:13:34
	(b) (4)	

US3522274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 07:58:52

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:36:22
User entered 'chest x-ray'	(b) (4) Yaman Ahmed (b) (4)	22 Apr 2021 18:13:34
	(b) (4)	

US3522274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 07:58:52

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	26 Apr 2021 12:36:22
User entered 'Adverse Event (AE)'	(b) (4) Yaman Ahmed (b) (4)	22 Apr 2021 18:13:34
	(b) (4)	

US3522274

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 07:58:52

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4) (b) (4)	26 Apr 2021 12:36:22
User entered empty.	Yaman Ahmed (b) (4) (b) (4)	22 Apr 2021 18:13:34

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'USA-US131-2021-MRNA-1273-P301000009'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:11:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:51:39
Un-reviewed for Safety.	System	12 Mar 2021 18:44:58
Signature has been broken.	System	12 Mar 2021 18:44:58
User entered 'Yes (Y)'	System	12 Mar 2021 18:44:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Marcus'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Paul'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Zervos'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Kilgore'	System	04 Mar 2021 15:47:21



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '2799 West Grand Blvd'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Detroit'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered empty.	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'MI'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '48202'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 18:51:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'US'	(b) (4) System	04 Mar 2021 15:50:27

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 20:23:32
User entered '6'	System	14 Apr 2021 13:30:23
User entered '5'	System	12 Apr 2021 17:10:58
User entered '4'	System	29 Mar 2021 17:30:09
User entered '3'	System	16 Mar 2021 13:37:32
User entered '2'	System	12 Mar 2021 18:52:03
User entered '1'	System	04 Mar 2021 15:50:27

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'USA-US131-2021-MRNA-1273-P301000009'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:11:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:51:39
Un-reviewed for Safety.	System	12 Mar 2021 18:44:58
Signature has been broken.	System	12 Mar 2021 18:44:58
User entered 'Yes (Y)'	System	12 Mar 2021 18:44:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Marcus'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Paul'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Zervos'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Kilgore'	System	04 Mar 2021 15:47:21



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '2799 West Grand Blvd'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Detroit'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered empty.	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'MI'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '48202'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 18:51:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'US'	(b) (4) System	04 Mar 2021 15:50:27

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 20:23:32
User entered '6'	System	14 Apr 2021 13:30:23
User entered '5'	System	12 Apr 2021 17:10:58
User entered '4'	System	29 Mar 2021 17:30:09
User entered '3'	System	16 Mar 2021 13:37:32
User entered '2'	System	12 Mar 2021 18:52:03
User entered '1'	System	04 Mar 2021 15:50:27

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:58:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered '04/Mar/2021 15:50'	(b) (4) System	04 Mar 2021 15:50:27

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:58:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 18:51:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:27



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'USA-US131-2021-MRNA-1273-P301000009'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:11:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:51:39
Un-reviewed for Safety.	System	12 Mar 2021 18:44:58
Signature has been broken.	System	12 Mar 2021 18:44:58
User entered 'Yes (Y)'	System	12 Mar 2021 18:44:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Marcus'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Paul'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Zervos'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Kilgore'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '2799 West Grand Blvd'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Detroit'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered empty.	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'MI'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '48202'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 18:51:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'US'	(b) (4) System	04 Mar 2021 15:50:27

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 20:23:32
User entered '6'	System	14 Apr 2021 13:30:23
User entered '5'	System	12 Apr 2021 17:10:58
User entered '4'	System	29 Mar 2021 17:30:09
User entered '3'	System	16 Mar 2021 13:37:32
User entered '2'	System	12 Mar 2021 18:52:03
User entered '1'	System	04 Mar 2021 15:50:27



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:58:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:11:42
User entered '12/Mar/2021 13:51'	(b) (4) System	12 Mar 2021 18:52:03

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:58:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:11:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:37:35
User entered '1'		12 Mar 2021 18:52:03

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'USA-US131-2021-MRNA-1273-P301000009'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:11:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:51:39
Un-reviewed for Safety.	System	12 Mar 2021 18:44:58
Signature has been broken.	System	12 Mar 2021 18:44:58
User entered 'Yes (Y)'	System	12 Mar 2021 18:44:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Marcus'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Paul'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Zervos'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Kilgore'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '2799 West Grand Blvd'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Detroit'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered empty.	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'MI'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '48202'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6)'	System	04 Mar 2021 15:47:21



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 18:51:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'US'	(b) (4) System	04 Mar 2021 15:50:27

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

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Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 20:23:32
User entered '6'	System	14 Apr 2021 13:30:23
User entered '5'	System	12 Apr 2021 17:10:58
User entered '4'	System	29 Mar 2021 17:30:09
User entered '3'	System	16 Mar 2021 13:37:32
User entered '2'	System	12 Mar 2021 18:52:03
User entered '1'	System	04 Mar 2021 15:50:27

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:58:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:11:42
User entered '16/Mar/2021 09:37'	(b) (4) System	16 Mar 2021 13:37:32

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:58:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:11:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 13:37:35
User entered 'I'		16 Mar 2021 13:37:32

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'USA-US131-2021-MRNA-1273-P301000009'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:11:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:51:39
Un-reviewed for Safety.	System	12 Mar 2021 18:44:58
Signature has been broken.	System	12 Mar 2021 18:44:58
User entered 'Yes (Y)'	System	12 Mar 2021 18:44:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Marcus'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Paul'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Zervos'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Kilgore'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '2799 West Grand Blvd'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Detroit'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered empty.	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'MI'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '48202'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 18:51:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'US'	(b) (4) System	04 Mar 2021 15:50:27

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 20:23:32
User entered '6'	System	14 Apr 2021 13:30:23
User entered '5'	System	12 Apr 2021 17:10:58
User entered '4'	System	29 Mar 2021 17:30:09
User entered '3'	System	16 Mar 2021 13:37:32
User entered '2'	System	12 Mar 2021 18:52:03
User entered '1'	System	04 Mar 2021 15:50:27

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:58:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:37:42
User entered '29/Mar/2021 13:30'	(b) (4) System	29 Mar 2021 17:30:09

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:58:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 17:10:27
User signature succeeded.	Marcus Zervos (b) (4)	05 Apr 2021 11:37:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 17:30:09

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'USA-US131-2021-MRNA-1273-P301000009'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:11:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:51:39
Un-reviewed for Safety.	System	12 Mar 2021 18:44:58
Signature has been broken.	System	12 Mar 2021 18:44:58
User entered 'Yes (Y)'	System	12 Mar 2021 18:44:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Marcus'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Paul'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Zervos'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Kilgore'	System	04 Mar 2021 15:47:21



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '2799 West Grand Blvd'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Detroit'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered empty.	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'MI'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '48202'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 18:51:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'US'	(b) (4) System	04 Mar 2021 15:50:27

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 20:23:32
User entered '6'	System	14 Apr 2021 13:30:23
User entered '5'	System	12 Apr 2021 17:10:58
User entered '4'	System	29 Mar 2021 17:30:09
User entered '3'	System	16 Mar 2021 13:37:32
User entered '2'	System	12 Mar 2021 18:52:03
User entered '1'	System	04 Mar 2021 15:50:27

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 07:58:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:34:14
User entered '12/Apr/2021 13:10'	(b) (4) System	12 Apr 2021 17:10:58

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 07:58:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:23:09
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:34:14
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 17:10:58



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'USA-US131-2021-MRNA-1273-P301000009'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:11:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:51:39
Un-reviewed for Safety.	System	12 Mar 2021 18:44:58
Signature has been broken.	System	12 Mar 2021 18:44:58
User entered 'Yes (Y)'	System	12 Mar 2021 18:44:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Marcus'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Paul'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Zervos'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Kilgore'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '2799 West Grand Blvd'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Detroit'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered empty.	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'MI'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '48202'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 18:51:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'US'	(b) (4) System	04 Mar 2021 15:50:27

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 20:23:32
User entered '6'	System	14 Apr 2021 13:30:23
User entered '5'	System	12 Apr 2021 17:10:58
User entered '4'	System	29 Mar 2021 17:30:09
User entered '3'	System	16 Mar 2021 13:37:32
User entered '2'	System	12 Mar 2021 18:52:03
User entered '1'	System	04 Mar 2021 15:50:27



US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 07:58:52

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:34:14
User entered '14/Apr/2021 09:30'	(b) (4) System	14 Apr 2021 13:30:23

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 07:58:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 20:23:09
User signature succeeded.	Marcus Zervos (b) (4)	14 Apr 2021 22:34:14
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 13:30:23

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'USA-US131-2021-MRNA-1273-P301000009'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Serious

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Death

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	19 Mar 2021 18:11:42
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Mar 2021 18:51:39
Un-reviewed for Safety.	System	12 Mar 2021 18:44:58
Signature has been broken.	System	12 Mar 2021 18:44:58
User entered 'Yes (Y)'	System	12 Mar 2021 18:44:58
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Yes (Y)'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21



US3522274

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Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'No (N)'	System	04 Mar 2021 15:47:21

US3522274

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Marcus'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Paul'	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Zervos'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'Kilgore'	System	04 Mar 2021 15:47:21

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Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

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Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '2799 West Grand Blvd'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 07:58:52

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered 'Detroit'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6) '	System	04 Mar 2021 15:47:21

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

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[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered empty.	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered 'MI'	System	04 Mar 2021 15:47:21

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Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
	(b) (4)	
Un-reviewed for Safety.	System	29 Apr 2021 20:23:32
Signature has been broken.	System	29 Apr 2021 20:23:32
User entered '48202'	System	29 Apr 2021 20:23:32
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 15:50:18
User entered (b) (6)'	System	04 Mar 2021 15:47:21



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Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 18:51:39
User signature succeeded.	Marcus Zervos (b) (4)	05 Mar 2021 15:43:53
User entered 'US'	(b) (4) System	04 Mar 2021 15:50:27

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Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form

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[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '7'	System	29 Apr 2021 20:23:32
User entered '6'	System	14 Apr 2021 13:30:23
User entered '5'	System	12 Apr 2021 17:10:58
User entered '4'	System	29 Mar 2021 17:30:09
User entered '3'	System	16 Mar 2021 13:37:32
User entered '2'	System	12 Mar 2021 18:52:03
User entered '1'	System	04 Mar 2021 15:50:27

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (7)

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Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
User entered '29/Apr/2021 15:23'	(b) (4) System	29 Apr 2021 20:23:32

US3522274

Folder: SAE USA-US131-2021-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 07:58:52

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Marcus Zervos (b) (4)	29 Apr 2021 22:45:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:23:32